A PERFORMANCE EVALUATION OF THE PREGNANCY RISK ASSESSMENT MONITORING SYSTEM (PRAMS): VALIDATING RISK FACTORS OF PRETERM BIRTHS

by
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Abstract

Improving the health and well-being of mothers and infants is an important public health goal for the United States because it determines the health of the next generation. The Pregnancy Risk Assessment Monitoring System (PRAMS) is a CDC surveillance system that captures data on health-related indicators that influence maternal and infant health and seeks to better understand maternal behaviors and attitudes before, during and after pregnancy. This study will evaluate PRAMS as a national surveillance tool used for identifying pregnancy risk factors.

The study used a mixed methods design that addressed the following study aims:

Aim 1: To evaluate the strengths and limitations of PRAMS as a public health pregnancy surveillance system by assessing nine system attributes according to CDC's Guidelines for Evaluating Public Health Surveillance Systems.

Aim 2: To determine the validity and reliability of PRAMS self-reported health indicators by evaluating sensitivity, positive predictive value (PPV) and interrater agreement of selected proximate determinates of preterm births that are self-reported on the PRAMS questionnaire.

Study aim 1 used qualitative research strategies (i.e. document reviews and stakeholder interviews) to gather evidence regarding the performance of the PRAMS system. A thematic analysis identified several principal themes that evidenced the performance of the surveillance system and lead to the emergence of PRAMS' strengths and limitations. Out of the nine surveillance system attributes, six attributes were identified as strengths (flexibility, data quality, acceptability, sensitivity, representativeness and stability) and three attributes were identified as limitations (simplicity, positive predictive value and timeliness).

Study aim 2 examined the validity and reliability of Maryland's PRAMS by quantitatively evaluating sensitivity, positive predictive value (PPV) and interrater agreement of ten proximate determinates of preterm births that were self-reported on the PRAMS questionnaire. The quantitative measurements of study aim 2 lead to three study outcomes. First, PRAMS had excellent to moderate sensitivity. Second, PRAMS had poor PPV, with PPV performing consistently lower than sensitivity. Third, PRAMS had almost-perfect to substantial interrater agreement with state birth certificates on most self-reported indicators. Overall, study findings supported the conclusion that PRAMS is a satisfactory surveillance system that performs favorably for most surveillance system attributes.

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Chapter 1: Introduction

Maternal and Infant Health in the United States

Improving the health and well-being of mothers and infants is an important public health goal for the United States. It aligns with Healthy People 2030, a 10-year national framework to identify health priorities and improve the nation's health by shifting the focus from treating disease to preventing them[1]. Identifying health risks before and during pregnancy and focusing on preventing health complications can lead to healthier mothers, infants and consequently, a healthier next generation.

Nonetheless, each year there are thousands of infants born with serious health problems and some of these infants do not survive. Although the U.S. infant mortality rate has declined by 15% over the past decade, the United States continues to have one of the highest infant mortality rates among developed countries, 5.8 deaths per 1,000 live births in 2017 (Appendix 1) and 5.7 deaths 1,000 live births in 2018 [2] [3] [4]. Furthermore, the preterm birth rate rose for the fifth straight year in 2019, affecting 1 out of every 10 infants born in the United States[5]. By nearly every important measure of maternal and infant health, the United States is struggling to make much-needed gains to reduce the morbidity and mortality permeating through this subsection of the population.

To address these adverse outcomes, public health agencies, researchers, policymakers and medical providers must ask the critical questions: Why do these public health challenges persist? Who is most affected and why? What are the most effective and efficient means to achieve better health outcomes for American mothers and infants? For the past three decades, the Pregnancy Risk Assessment Monitoring System (PRAMS) has served as an essential source of data on the various

determinants that impact maternal and infant health and can inform answers to the aforementioned questions.

Pregnancy Risk Assessment Monitoring System (PRAMS) Overview

What is PRAMS?

The Pregnancy Risk Assessment Monitoring System (PRAMS) is a Centers for Disease Control and Prevention (CDC) initiative to reduce infant morbidity and mortality by influencing maternal behaviors before, during and immediately after pregnancy[6]. Developed in 1987, PRAMS is the only ongoing state-level, population-based surveillance system that provides data about pregnancy and the first few months after birth. It is a joint research project between state health departments and CDC's Division of Reproductive Health. CDC provides annual funding to participating states through a cooperative agreement, with supplemental funding contributed by the individual states. Since the inception of PRAMS, the number of participating states and areas has increased from 6 to 50, including 47 states, the District of Columbia, New York City and Puerto Rico (Appendix 2)[7]. PRAMS surveillance currently represents approximately 83% of all U.S. live births.

PRAMS Methodology

States are responsible for administering the PRAMS survey and collecting PRAMS data. The surveillance system randomly samples mothers who recently had a live birth. Each participating site draws a stratified systematic sample of 100 to 250 mothers every month from eligible live birth certificate files[8]. Women from selected groups are sampled at a higher rate to ensure adequate data are available in smaller but higher risk populations (i.e. low birth weight, race or ethnicity).

PRAMS is a mixed-mode (mail and telephone) survey that incorporates techniques developed to enhance response rates. These techniques are based on Dillman's tailored design method and include personalized mailing packages, use of response incentives and rewards, and repeated but varied contact attempts[9]. The primary data collection mode is mail, with telephone follow-up for mail non-respondents[10]. A series of mailings begin two to four months after delivery, and includes a pre-letter, an initial questionnaire packet, a tickler, and a second and third questionnaire packet for non-respondents. Telephone follow-ups are initiated for all mail non-respondents and staggered over different times of day and different days of the week for a total of 15 call attempts. The data collection cycle from the mailing of the pre-letter to the close of telephone follow-ups last approximately 60-95 days[8]. To-date, PRAMS has a minimum overall response rate threshold of 55% for release of data by CDC[11].

All participating sites use standard data collection procedures and instruments to allow for comparisons. The standardized data collection methodology is prescribed in the CDC Model Surveillance Protocol and has built-in flexibility so that participating sites can tailor PRAMS to meet their needs, including scheduling of mailings, appearance of mailing materials and use of response incentives and rewards[8].

PRAMS Questionnaire

The PRAMS questionnaire was initiated during an era of intense state and national interest in infant mortality, racial disparities reduction and public support of prenatal care program expansions, as well as a lack of state-specific information available to inform local and state program development and assessment[12]. The original PRAMS questionnaire was developed in 1987 (Phase 1) and has undergone several phase changes since its conception (Appendix 3). With

each phase, the questionnaire became more extensive as selected questions were revised, deleted or added. In 1996 (Phase 3), CDC coordinated the development of core questions and standard questions. Core questions are asked by all participating sites and include the following themes:

- Preconception care
- Content of prenatal care
- Medicaid and WIC participation
- Breastfeeding
- Contraceptive use
- Cigarette smoking and alcohol use
- Health insurance coverage
- Physical abuse
- Infant health care
- Attitudes and feelings about the most recent pregnancy

Standard questions cover core topics in more depth or cover topics that are not in the core questions but are of interest across multiple states. There are currently 200+ standard questions developed by CDC that states can select to include in their surveys. Standard questions, as well as core questions, allow for data collection using uniform indicators. States also have the option of creating state-developed questions to cover topics for which there are no core or standard questions. As a result, each participating site's PRAMS questionnaire is unique.

Since PRAMS uses a mixed-mode methodology, there are two types of questionnaires: the self-administered questionnaire used for mailing and the interviewer-administered questionnaire used for telephone follow-ups. Both questionnaires contain the same questions; however, some questions are formatted differently to facilitate the different mode of administration. Survey questionnaires and other materials are available in both English and Spanish.

Maryland's PRAMS

For the purpose of this study, Maryland was used as the sample state. The Maryland Department of Health started collecting PRAMS data in 2000 (Phase 4)[13]. Maryland used the PRAMS core

questions, as well as standard questions that are tailored to the state's needs. Topics included in Maryland's standard questions are:

- Assisted reproduction (fertility drugs)
- Flu vaccination
- Automobile safety
- Depression and anxiety
- Oral health
- Social services
- Prenatal care
- Contraception use

Maryland has a PRAMS Steering Committee that advises PRAMS staff in the development and selection of state-specific questions and on the use, dissemination and application of findings[13]. Findings are then used to guide recommendations for developing or modifying intervention programs and policy within the state of Maryland.

Study Aims

According to CDC, the Pregnancy Risk Assessment Monitoring System's primary goal is to figure out why some infants are born healthy and others are not[6]. PRAMS was designed 1) to identify groups of women and infants at high risk for health problems, 2) to monitor changes in health status, and 3) to measure progress toward goals in improving the health of mothers and infants. For the purpose of this study, there are two principal aims:

Aim 1: To evaluate the strengths and limitations of PRAMS as a public health pregnancy surveillance system by assessing nine system attributes according to CDC's Guidelines for Evaluating Public Health Surveillance Systems.

Aim 2: To determine the validity and reliability of PRAMS self-reported health indicators by evaluating sensitivity, positive predictive value (PPV) and interrater agreement of selected proximate determinates of preterm births that are self-reported on the PRAMS questionnaire.

Significance

Various maternal behaviors and experiences before, during and after pregnancy are associated with adverse health outcomes for both mother and infant[14]. For example, late or inadequate prenatal care is associated with poorer pregnancy outcomes such as low birthweight, preterm birth, and fetal or infant death[15]. Additionally, inadequate prenatal care might prevent or delay the diagnosis and treatment of medical conditions that may occur during pregnancy[14]. The abuse of certain licit and illicit drugs can have detrimental effects on a developing fetus[16]. Maternal malnutrition is another determinant of poor maternal and infant health outcomes and can lead to intrauterine growth restriction, preterm birth, and maternal and infant morbidity and mortality[17]. These are just a few of the known behaviors and experiences captured by PRAMS in an effort to prevent poor maternal and infant health outcomes.

PRAMS promotes the collection, analysis and dissemination of population-based data as it relates to pregnancy risk factors[10]. It allows for a more in-depth inquiry of reproductive health topics than what is currently possible from the more widespread but limited set of information available on birth certificates[12]. By enhancing information from birth certificates, PRAMS supports the use of data to develop new programs and policies aimed at improving the health of mothers and infants, evaluate existing programs and policies, develop educational materials for health care providers and the public, and contribute to general health knowledge[10]. It provides the opportunity to monitor the prevalence of behavioral risk factors and offers direction for targeted interventions. PRAMS

provides estimates on indicators that are not available from any other data sources (i.e. progress over time in terms of infant sleep position, unintended births and patterns of health insurance coverage)[10]. Furthermore, PRAMS data can be used to identify disparities, explore health outcomes by high-risk subpopulations and compare health indicators within and across states.

PRAMS data are used by academic researchers, nonprofit health organizations, state health departments, federal agencies and the general Maternal and Child Health (MCH) community. By participating in PRAMS, states can ask questions to gain a better understanding of the preconception and postpartum periods, in addition to the time during pregnancy. With this information, stakeholders can work to improve the health of future mothers and infants within their states and across the nation.

At the end of this study, recommendations will be proposed on how PRAMS can improve its performance as a national surveillance system and its effectiveness in identifying and monitoring high-risk pregnancies. Interested stakeholders may include the Centers for Disease Control and Prevention, Maryland's Department of Health, PRAMS Coordinators, MCH Directors, academic researchers, nonprofit health organizations, and other federal and state agencies. Should this study prove PRAMS to be a valid and effective pregnancy surveillance system, it could potentially encourage other countries to develop a similar pregnancy surveillance system with the goal of reducing maternal and infant morbidity and mortality globally.

Chapter 2: Literature Review

Evaluating Surveillance Systems

The World Health Organization (WHO) defines public health surveillance as "the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation and evaluation of public health practice"[18]. The evaluation of a surveillance system promotes the best use of data collection resources and assures that systems operate effectively[19]. A surveillance system evaluation verifies whether the system is useful for a particular public health initiative and is achieving the overarching goals of the public health program and the data collection objectives[19]. Public health surveillance systems should be evaluated periodically, and the evaluations should include recommendations for improving the quality, efficiency and usefulness of the surveillance system[20].

Surveillance systems vary widely in methodology, scope and objective. As a result, characteristics that are important to one system may be less important to another[21]. For example, efforts to improve certain attributes, such as the ability of a system to detect a health event (sensitivity), may detract from other attributes, such as simplicity or timeliness[21]. Therefore, the success of an individual surveillance system depends on the proper balance and priority of characteristics[21]. CDC recommends the evaluation of the following nine system attributes for public health surveillance systems: simplicity, flexibility, data quality, acceptability, sensitivity, predictive value positive, representativeness, timeliness and stability[20].

Evaluating PRAMS

The number of PRAMS evaluations in the literature was limited. In 2006, the U.S. Department of Health and Human Services (HHS) conducted a PRAMS program evaluation as a part of its

performance improvement initiative through the Office of the Assistant Secretary for Planning and Evaluation. The objectives were to inform the operational, analytic, translation and capacity-building functions of the current PRAMS system and to make them more efficient, effective and capable of meeting future needs[22]. The evaluation revealed that many of the study's recommendations were already incorporated into the PRAMS program operations[22]. Additionally, the evaluation findings showed that PRAMS is a strong and vibrant surveillance program facing a range of programmatic challenges[22].

A 2018 journal article from the American Public Health Association discussed the current strengths and growth opportunities of PRAMS. PRAMS was widely praised for its ability to inform national- and state-level policy and programming[23]. The article reported that PRAMS' strengths resulted from several factors including the range and depth of content and the ability to tailor survey administration by state[23]. By capturing information of a range of topics across the preconception, pregnancy and postpartum continuum, PRAMS allowed for the exploration of associations between health-related behaviors and attitudes before, during and shortly after pregnancy, as well as health outcomes for both mothers and infants[23].

The demonstrable value of PRAMS data at both the national and state levels was well documented, but there were opportunities to expand the utility of the system. Although designed to maintain data quality and provide states with clear performance objectives, PRAMS had a minimum overall response rate threshold policy for public data release[11]. The threshold began at 70% for years 2006 and earlier. Beginning in 2007, the threshold changed to 65% and beginning in 2012, it was changed to 60%[11]. In 2015, the threshold was lowered to 55% and had remained constant[11]. It was possible that states with low response rates did not meet the threshold in a given year and consequently, availability of PRAMS data may vary from year to year[23]. The application of a

response rate threshold may impair trend analysis and hinder the use of data to inform public policy and monitoring of public investments to the fullest extent possible[23].

Another area of opportunity for the PRAMS surveillance system was data timeliness and accessibility[23]. The current data cycle was approximately two years – PRAMS 2018 data was available as of January 2020[11]. This two-year delay in data can create challenges for states who need to use the data for timely decision-making in response to current and emergent public health threats to the maternal and infant health population[23]. Ensuring timely data access in formats that can be easily retrieved by diverse user groups continues to be a challenge for the PRAMS system[23].

PRAMS in Use

PRAMS in Practice

PRAMS provides state-specific data used to monitor health behaviors, access to care and receipt of services among recently pregnant women[10]. For example, PRAMS data has been used to monitor progress towards Healthy People 2020 objectives[24], Title V National Performance Measures for safe sleep and preventive dental visits[25], preconception health and health care indicators[26], and selected performance measures for various public health programs and initiatives. The state of Maryland used PRAMS data to reveal the alarming percentage of mothers that reported being physically abused by a partner either during or in the year prior to pregnancy[27]. This trend in intimate partner violence (IPV) among mothers prompted the Maternal and Child Health Bureau of the Maryland Department of Health and Mental Hygiene to establish a Maryland IPV Task Force[27]. The Task Force facilitated the development of a three-question IPV screening tool for use by health care providers and included resources for immediate referrals. Since the adoption of the IPV screening tool in 2013, hundreds of pledges have been collected from

providers to integrate IPV screenings and referrals into their work[27]. This is one of many examples of how Maryland uses PRAMS in practice to plan public health programs.

Another example is that PRAMS data has been used to reduce sleep-related infant deaths in Maryland by analyzing the prevalence of unsafe sleeping environments and strengthening parental education on sudden unexpected infant death (SUID)[27]. SUID is an significant cause of death among infants in the United States and is defined by the Office of the Chief Medical Examiner as "... the sudden death of an infant less than one year of age that cannot be explained after a thorough investigation is conducted, including a complete autopsy, examination of the death scene, and a review of the clinical history"[28]. Between 2002 and 2006, Baltimore City Child Fatality Review identified 89 unexpected infant deaths that occurred during sleep[27]. PRAMS revealed that among all Maryland jurisdictions, Baltimore City had the lowest prevalence of mothers placing infants to sleep on their backs, a practice known to reduce the risk of SUID[27]. In 2010, the Baltimore City Health Department launched a parent education campaign to teach parents about safe sleep for infants as part of the B'More for Healthy Babies initiative to reduce infant mortality[27]. Since the Baltimore City Health Department began safe sleep messaging in 2010, preliminary data collected during 2009-2012 suggest that sleep-related infant deaths have decreased annually[27]. Because of its success, the Maryland Department of Health and Mental Hygiene distributed Baltimore City's materials statewide to delivery hospitals, home visiting programs, local health departments and WIC sites[27].

PRAMS in Research

PRAMS is used by researchers to investigate emerging issues in the field of reproductive health[29]. By measuring prevalence of maternal behaviors using PRAMS data, researchers enhance the

understanding of the relations between behavior and outcomes[14]. A 2016 study by Wouk et al. conducted a multivariable logistic regression analysis from the 2010-2011 PRAMS examining the relationship between postpartum depression (PPD) and breastfeeding practices. The study found that PPD and anxiety symptoms were associated with reduced breastfeeding initiation, duration and intensity[30]. In 2018, Brunner Huber et al. used PRAMS data from Mississippi and Tennessee to determine the associations between interbirth intervals and pregnancy complications and outcomes. The study's results showed that women with short interbirth intervals had 3-fold, statistically significant increased odds of complications[31]. Study findings provided further support for encouraging women to space their pregnancies appropriately and to seek family planning services so that closely spaced pregnancies and unintended pregnancies can be avoided[31].

PRAMS data can be linked to birth certificate files and has the potential to capture demographic information of participants. This data allows researchers to study racial, ethnic and socioeconomic disparities in adverse birth outcomes. A 2018 study by Nguyen et al. used data drawn from the 2012-2014 PRAMS to examine racial, ethnic and socioeconomic variations in receiving comprehensive prenatal health education and education about human immunodeficiency virus (HIV) testing, breastfeeding, alcohol, and smoking cessation from health care providers. Study results found that women from racial or ethnic minorities and socioeconomically disadvantaged groups reported receiving higher levels of prenatal health education compared with women of advantaged groups[32]. These results were attributed to health care providers targeting health education to minority women and those from low socioeconomic backgrounds as these groups have been consistently identified as having greater risks for adverse birth outcomes[32]. Bower et al. conducted a cross-sectional analysis from the 2004-2012 PRAMS and found that the emotional effect of experiences of racism contribute to preterm birth among non-Hispanic Black women[33].

PRAMS in Policy

PRAMS data can be used to inform and direct policy decisions. For example, Minnesota PRAMS data from 2009-2010 reported that approximately 1 of 10 mothers in Greater Minnesota (a rural area of the state) did not receive prenatal care as early in their pregnancy as they wanted. Minnesota's PRAMS data influenced development of state Medicaid policies as it related to prenatal care. Specifically, in 2013, the Minnesota state legislature passed a bill to provide Medicaid payment for services from a certified doula for low-income pregnant women in Minnesota[34]. The use of Minnesota PRAMS data contributed to the state's understanding of how doula services can be used to target rural and underserved women, especially in the American Indian community.

Another example of PRAMS in policy took place in Oregon. Oregon's 1999 PRAMS data revealed that although 90% of mothers initiated breastfeeding, many women discontinued breastfeeding when they returned to work because of barriers in the workplace, including inflexible work hours, lack of privacy for breastfeeding or expressing milk, and lack of storage for expressed breastmilk[35]. Interested in developing ways to reduce breastfeeding barriers in the workplace, Oregon Public Health Division worked to identify and refurbish space that allowed state employees to breastfeed at work. Their findings were presented to the state legislature and helped create Oregon House Bill 2372, known as "Rest Periods for Expression of Breast Milk," which required larger employers to provide time and space for breastfeeding[35]. Subsequently, through the sponsorship of Oregon's U.S. Senator, features of the Oregon law were incorporated into the 2010 Patient Protection and Affordable Care Act[35].

Key Determinants of Maternal and Child Health

According to the Office of Disease Prevention and Health Promotion, there is a range of biological, social, environmental, and physical factors that are linked to maternal, infant and child health outcomes[36]. These include race, ethnicity, age, socioeconomic factors such as income level, educational attainment, medical insurance coverage, access to medical care, pre-pregnancy health and general health status[36]. Some of these factors can affect and compound with others, creating a rippling effect. For example, factors ranging from age to medical insurance coverage affect a women's general health status and in turn, a women's health status directly influences her risk of pregnancy complications and her infant's cognitive and physical development[36].

According to CDC, the five leading causes of infant death in 2018 were: 1) birth defects, 2) preterm births and low birth weight, 3) maternal pregnancy complications, 4) sudden infant death syndrome, and 5) injuries[4]. Many of these causes are preventable and are directly affected by maternal health and behavior, as well as the availability of quality obstetrical/neonatal care. Lorenz et al.'s assessment of infant mortality in the United States indicated that maternal smoking, teen pregnancy, advanced maternal age, maternal obesity and disadvantaged socioeconomic status are a few of the major factors associated with preterm births, the second leading cause of infant death[37]. Furthermore, there are racial and ethnic disparities, as well as geographic disparities, that contribute to infant mortality rates (Appendixes 4 and 5)[37].

The most notable disparity in maternal and child health is defined by race. In the United States, the maternal mortality rates of Black women range from three to four times the rate of their White counterparts – 43.5 deaths per 100,000 live births among Black women versus 12.7 deaths per 100,000 live births among White women during 2011-2013 (Appendix 6)[38]. In Maryland, Black

women have a maternal mortality rate 3.7 times greater than White women (Appendix 7)[39]. Women of color tend to have poorer access to high quality reproductive health information and services than White women, are discriminated against in the healthcare system, and experience higher rates of disrespect and abuse[40]. Furthermore, research suggest that maternal stress associated with experiences of racial discrimination can increase the risk of negative perinatal outcomes, including preterm birth and delivery of low birth weight infants in women of color[41].

Maternal and infant outcomes also vary significantly by socioeconomic status, geography and access to care. States with higher levels of poverty, immigrant population and cesarean rates experience significantly higher maternal mortality ratios than the national average[42]. Women receiving no prenatal care are three to four times more likely to have a pregnancy-related death than women who receive prenatal care[43]. Approximately, 23% of all U.S. women do not receive early and adequate prenatal care; this number increases to 32% among African Americans and 38% among American Indian or Alaska Native women (Appendix 8)[44].

Preterm Births

According to the World Health Organization, preterm is defined as infants born alive before 37 weeks of pregnancy are completed[45]. Preterm birth is a risk factor for short- and long-term adverse health outcomes. Short-term, it is the leading cause of neonatal death and the second cause of death in children younger than 5 years of age[46]. Long-term, it is associated with increased risk of hypertension, cardiovascular and cerebrovascular diseases, type 2 diabetes, chronic kidney disease, asthma and abnormalities in pulmonary function, and neurocognitive disorders[47].

There are a series of maternal factors identified to have impact on the risk of preterm birth. Some of these factors are non-modifiable, such as history of preterm births, extremes in maternal age

(<19 and >35 years), multiple pregnancies, ethnicity and family history, and genetics[48]. Researchers estimate that after one preterm birth, the risk of another is three times higher[49]. The increased risk of preterm birth pertaining to very young women is related to the fact that their reproductive organs are not yet fully developed. In the case of women over 35 years of age, the concern is related to aging and increased risk of pregnancy complications. Moreover, a mother's general health directly affects the course, duration and outcome of a pregnancy. Murphy et al. claims that a mother's illness or disease has influence on premature birth in 25% of cases[50].

Other maternal factors are modifiable, such as sociodemographic status, body mass index (BMI), obesity, smoking, substance abuse, short inter-pregnancy interval, late or no prenatal care, and the use of assisted reproductive technologies[48]. Sociodemographic factors such as maternal education, material status, professional career, nutritional status and stress are known to increase the risk of preterm birth[49]. Assisted reproductive technology can lead to more frequent pregnancies and greater risk of obstetric complications[49]. In addition, environmental factors such as air pollution and stimulants (i.e. smoking and drinking alcohol) have impact on preterm delivery risk[49].

Defining preterm risk factors is important to identifying groups of women who are at greater risk of premature births and applying appropriate and timely preventive measures[49]. By identifying pregnancies that are high-risk, extra attention and resources can be given to those mothers who need the most care in order to prevent poor outcomes. Actions can be taken to increase a woman's chance of having a baby with the best health possible, such as receiving early and regular prenatal care, managing health conditions and adopting healthy behaviors before becoming pregnant[51].

Chapter 3: Conceptual Framework

The published CDC Guidelines for Evaluating Surveillance Systems was selected to construct the study's conceptual framework because it provided standards for assessing the performance of public health surveillance systems. These guidelines are intended to organize the evaluation of surveillance systems with a focus on how well systems operate to meet its purpose and objectives. CDC defined nine attributes that apply to public health surveillance systems. These attributes are characteristics used to describe surveillance systems and to judge how well they perform and function. Although CDC is a public health agency for the United States, these surveillance system attributes are used globally to evaluate surveillance systems and their performance[52 53].

Both study aims evaluated PRAMS using the following nine surveillance system attributes:

Table 1: CDC Surveillance System Attributes and Definition

System Attribute	Definition
1. Simplicity	The ease of a system's structure and operations.
2. Flexibility	The ability to adapt to changing information needs or operating conditions with little additional time, personnel or allocated funds.
3. Data Quality	The ability to reflect the completeness and validity of the data recorded in the surveillance system.
4. Acceptability	The ability to reflect the willingness of persons and organizations to participate in the surveillance system.
5. Sensitivity	The ability of the surveillance system to detect the proportion of cases of a health-related event and the ability to monitor changes in the number of events over time.

System Attribute	Definition
6. Predictive Value Positive (PVP)	The proportion of reported cases that actually have the health-related event under surveillance.
7. Representativeness	The ability to accurately describe the occurrence of a health-related event over time and its distribution in the population by place and person.
8. Timeliness	The ability to reflect the speed between steps in a surveillance system.
9. Stability	The reliability (the ability to collect, manage and provide data properly without failure) and availability (the ability to be operational when it is needed) of a surveillance system.

Source: German et al (2001)

Chapter 4: Methods – Study Aim 1

Research Question

The first research question guiding this dissertation is: What are the strengths and limitations of the Pregnancy Risk Assessment Monitoring System (PRAMS) as a public health surveillance system for pregnancy risk?

Study Design

Study aim 1 was a descriptive, evaluative study of the Pregnancy Risk Assessment Monitoring System (PRAMS) using the Centers for Disease Control and Prevention (CDC) guidelines for evaluating public health surveillance systems. The PRAMS system was evaluated using a qualitative thematic study design that gathered credible evidence on PRAMS' performance on nine system attributes described by CDC guidelines. This study began with a document review, followed by stakeholder interview research. This methodological approach was selected so that gathered evidence came from reliable, valid and informative sources. The sequencing of data collection allowed for stakeholder interviews to validate and shed further light on information found in the document review.

Inclusion Criteria

The study setting included all U.S. states/areas participating in PRAMS. As mentioned, there are a total of 50 states and areas currently participating in PRAMS. This includes 47 states, the District of Columbia, New York City and Puerto Rico.

Sources of Data

Data for study aim 1 was collected using two qualitative research strategies. First, information on PRAMS system attributes was collected through a document review. The document review was a

way of collecting, analyzing, interpreting and organizing data by reviewing existing documents[54]. Furthermore, it allowed the study to gather historical and current information about PRAMS found in public records. For the purpose of this study, the document review consisted of a total of 55 documents from various electronic sources. Types of documents included program descriptions, annual reports, surveillance reports, summary briefs, journal articles, testimonials and protocol manuals. All documents used in this study are listed in Appendix 20. The following table is a breakdown of the documents by source:

Table 2: Document Review Sources

Document Source	# of Documents
Centers for Disease Control and Prevention Website	11
State Health Departments Websites	18
Journals	14
PRAMS 2018 Model Protocol	12

Source: Author's calculation

Second, information from the document review was supplemented with stakeholder interview research. Once the document review was completed, semi-structured interviews were conducted to expound and enhance information regarding PRAMS' surveillance system attributes. A combination of open-ended and closed-ended questions were adapted from CDC's Guidelines for Evaluation of Public Health Surveillance Systems. The purpose of the stakeholder interviews was to further investigate PRAMS system attributes by filling in information gaps and validating information found during the document review. The interview guide used for this study is presented in Appendix 21 and includes the randomized selection of participants, recruitment efforts, oral consent and interview questions. Study participants included 20 stakeholders who were identified by using purposive sampling techniques based on their involvement with the PRAMS surveillance system. Key stakeholders recruited to participate in the study included state

PRAMS Coordinators and Title V Maternal and Child Health (MCH) Directors. PRAMS coordinators administer the PRAMS survey, use the PRAMS data, and have oversight of their local PRAMS program. Each state had one PRAMS Coordinator and their contact information was available on CDC's PRAMS website. Title V Maternal and Child Health (MCH) Directors use PRAMS data for a variety of administrative and assessment purposes to support funding for states to improve the health of mothers and children. Contact information for the Title V Directors was available on the Association of Maternal and Child Health Programs (AMCHP) website. The following 17 sites engaged in the study and participated in the stakeholder interviews:

- Alaska
- Colorado
- Delaware
- Georgia
- Kentucky
- Louisiana
- Maine
- Mississippi
- Missouri
- Nebraska
- North Dakota
- Oregon
- Puerto Rico
- Rhode Island
- South Carolina
- Utah
- Wisconsin

Table 3 lists the breakdown of stakeholders by title:

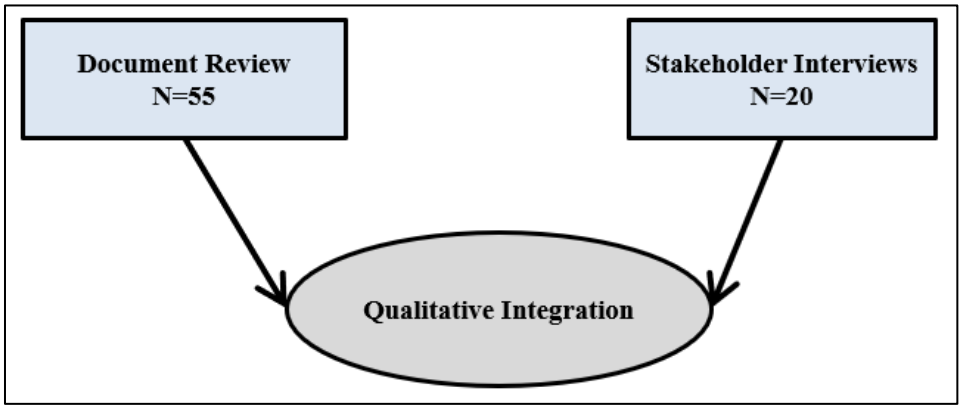
Table 3: Stakeholder Interviewees by Title

Title	# of Stakeholders
PRAMS Project Coordinator	5
Title V MCH Director	5
PRAMS Principal Investigator	3
PRAMS Project Director	2
Maternal and Infant Health Program Manager	2
Title V Analyst	1
MCH Epidemiologist	1
State Surveillance Manager	1

Source: Author's calculation

Figure 1 is a visual representation summarizing the study's qualitative integration of the document review and stakeholder interviews.

Figure 1: Qualitative Integration, Summary



Source: Author's construction

Protection of Human Subjects

The evaluation of the Pregnancy Risk Assessment Monitoring System and the study aims are under the support of the Johns Hopkins' Institutional Review Board (IRB) study number 00013986. The IRB confirmed that personal or private information was not collected during this study. The research team took precautions to protect participants by using de-identified data, password protected devices and secured data storage. The study de-identified data by replacing identifiers (i.e. name and state) with non-identifying terms (i.e. numbers) and creating a confidential crosswalk for the non-identifying terms. The study data was not shared with other parties outside of the research team. There were no physical, psychological, emotional, social, legal or economic risks to any person associated with this study.

Study Variables

Table 4 lists the nine PRAMS attributes that were adopted as the study's variables, as well as their corresponding characteristics.

Table 4: PRAMS Attributes & Characteristics

System Attribute	Attribute Characteristics
1. Simplicity	• Amount and type of data on cases (i.e. demographics, behavioral, attitudes, environment) • Level of integration with other systems • Method of collecting PRAMS data • Amount of necessary follow-up • Method of managing, analyzing and disseminating data • Staff training requirements • Time spent on maintaining the PRAMS program
2. Flexibility	• Accommodation of new health-related events • Changes in definitions • Variations in reporting sources
3. Data Quality	• Percentage of "unknown" or "blank" responses • Clarity of PRAMS survey • Completeness of survey forms
4. Acceptability	• PRAMS participation rate • State reporting rates • Dissemination of aggregate data back to states and other interested parties • PRAMS requirements for data collection • Ability to protect privacy and confidentiality
5. Sensitivity	• Ability for respondents to understand survey questions and correctly identify their status • Willingness of respondents to report their status
6. Predictive Value Positive (PVP)	• Confirmation of cases reported through the PRAMS surveillance system • Prevalence of health-related event
7. Representativeness	• Characteristics of the population • Identification of population subgroups • Measurement of risk factors over time

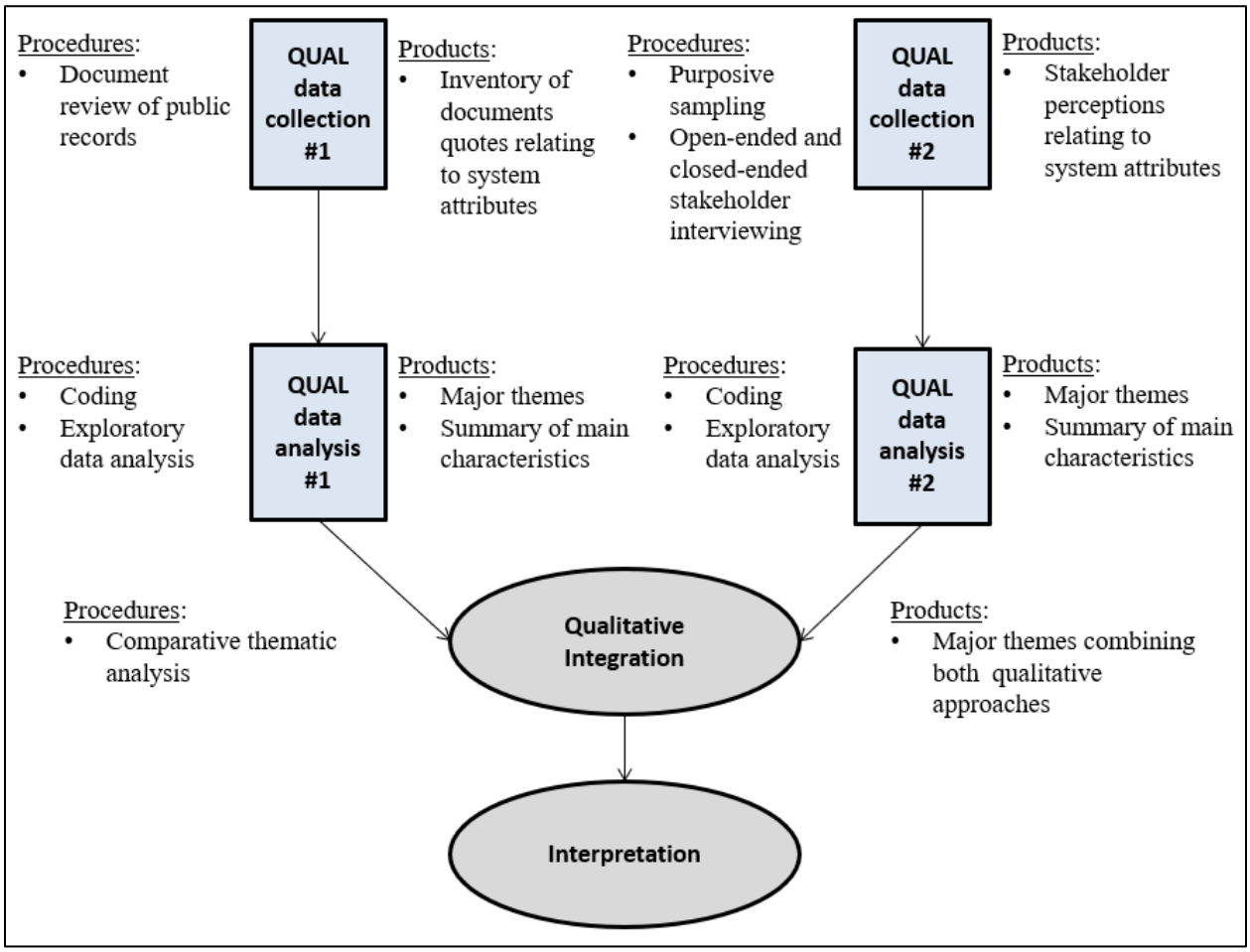
System Attribute	Attribute Characteristics
8. Timeliness	• Time intervals between steps in PRAMS methodology • Time required to identify trends
9. Stability	• Percentage of time the system is operating fully • Scheduled and unscheduled downtimes • Dedicated resources

Source: Author's construction based on German et al (2001)

Analysis Plan

For study aim 1, a qualitative thematic analysis was adopted to assess PRAMS' system attributes using information provided from the document review and stakeholder interview research. Findings from the document review were combined with interview responses as a means of triangulation – seeking convergence and corroboration through the use of different data sources, increasing the credibility of the study. The expectation of triangulation was that merging the results of two qualitative approaches will lead to a better understand of PRAMS' strengths and limitations as a public health surveillance system for pregnancy risk. During both research methods, information was extracted and coded into emerging themes based on the nine system attributes identified for the study. Like other analytical methods in qualitative research, the document review and stakeholder interviews required that data be examined and interpreted in order to elicit meaning and gain understanding. A comparative thematic analysis was used to identify patterns in the data and important information that informed the research question. Figure 2 shows a detailed diagram of the qualitative integration used for the study's thematic analysis.

Figure 2: Qualitative Integration, Detailed



Source: Author's construction

Chapter 5: Results & Discussion– Study Aim 1

Results

For each surveillance system attribute, several key themes were discovered through the study's thematic analysis. A total of 36 key themes were identified across all nine attributes. Table 5 presents the list of key themes by attribute. Verbatim quotations from stakeholders in support of the key themes are provided in Appendix 22. In-depth details of all themes are provided in Appendixes 23-31.

Table 5: Key Themes by Attribute

Attribute	Key Themes
Simplicity	1. Program Structure 2. Staff Training Requirements 3. Start-Up Activities 4. Data Collection & Management 5. Data Analysis 6. Level of Integration with Other Data Sources
Flexibility	1. System Tailored Design & Methodology 2. Technology 3. Questionnaire Customization 4. PRAMS Questionnaire Revision 5. Supplements 6. Partnerships
Data Quality	1. Quality Control 2. IRB Approval 3. Data Source 4. Data Completeness 5. Response Rate Threshold & Sample Sizes
Acceptability	1. Respondent Participation 2. Site Participation 3. Privacy & Confidentiality 4. Public Health Importance

Attribute	Key Themes
Sensitivity	1. Willingness to Report Status 2. Ability to Understand Questions & Correctly Identify Status 3. Validation of Data Collected
Positive Predictive Value (PPV)	1. Confirmation of Cases 2. Prevalence of Health-Related Events
Representativeness	1. Generalizability 2. Population of Interest 3. Errors and Biases
Timeliness	1. Surveillance System Time Intervals 2. Identification of Trends and Intervention Effectiveness 3. Start-Up and Revision Timelines
Stability	1. System Longevity & Utilization 2. Data Release & Availability 3. Dedicated Resources 4. Scheduled & Unscheduled Downtime

Source: Author's construction

Out of the nine surveillance system attributes, the study identified six attributes as strengths of the PRAMS system. These attributes were flexibility, data quality, acceptability, sensitivity, representativeness and stability. These attributes were identified as strengths because the study gathered credible evidence regarding the attributes' satisfactory performance in the PRAMS surveillance system. Each attribute had unique considerations for evaluation and PRAMS displayed favorable characteristics for the majority of those considerations.

The study findings identified the remaining three attributes as limitations of the PRAMS surveillance system. These attributes were simplicity, positive predictive value and timeliness. These attributes were identified as limitations because study findings suggested deficiencies in the performance of these attributes as it related to the PRAMS surveillance system. Although all nine attributes had distinct shortcomings in the PRAMS system, PRAMS's performance in the areas of

simplicity, positive predictive value and timeliness were substandard compared to the remaining attributes. Table 6 is a summary report of PRAMS's performance by attribute. Study findings for each system attribute are described below.

Table 6: Summary Report of PRAMS' Performance by Attribute

Attribute	PRAMS' Performance
Simplicity	Complex
Flexibility	Flexible
Data Quality	High data quality
Acceptability	Widely acceptable
Sensitivity	Sensitive
Positive Predictive Value (PPV)	Likely low
Representativeness	Representative
Timeliness	Untimely for some objectives
Stability	Relatively stable

Source: Author's construction

5.1. Simplicity – Limitation

The simplicity of a public health surveillance system takes into consideration its structure and ease of operations. Eleven out of twenty stakeholders agreed that PRAMS was a complex and multi-dimensional surveillance system. Stakeholder consensus was consistent with document review findings that pointed to PRAMS as being an intricate system with multiple components. PRAMS's structure was prescribed by the PRAMS Model Protocol, a set of standardized procedures and processes used to institutionalize PRAMS in participating sites and provide documentation to inform and guide users[55]. The protocol presented many of the components that make up the PRAMS system (i.e. Personnel, Training, Steering Committee, Sampling, Data Collection, Data

Management, Analysis, Use, etc.)[55]. All these components must work in tandem with one another to contribute to the overall success of the system.

Regarding PRAMS' ongoing operations, the methods of collecting, managing, analyzing and disseminating data were robust, requiring significant time and effort from staff. PRAMS had proven itself to be resource-intensive, requiring numerous, dedicated FTEs to support ongoing operations, including external contractors for sites that outsourced PRAMS operations. Shulman (2018) observed that there have been recent increases in the number of states contracting out data collection activities[10]. In 2016, 12% of states contracted out all data collection activities, 51% contracted out telephone follow-up activities only, and the remaining 37% conducted all activities at the health department[10]. For most participating sites, stakeholders reported that the PRAMS program required additional resources than what were allocated by CDC in order to adhere to standard protocol, maintain data quality and successfully operate the system.

PRAMS was identified as time-intensive, requiring significant time and effort to establish the surveillance system, as well as maintain ongoing data collection activities on an annual basis (i.e. mailings, call attempts, entering data, batching, etc.). For example, PRAMS placed enormous emphasis on follow-up processes to increase response rates among participants, exhibited by its multiple mailing and telephone attempts[56]. These varied attempts increased the complexity of the system, often requiring simultaneous follow-up attempts for 100-250 participants each month. Although PRAMS utilized the PRAMS Integrated Data System (PIDS) to alleviate the burden of data collection and had support from CDC, it still required in-depth, annual staff training on the collection, management and analysis of PRAMS data as outlined in the PRAMS Model Protocol[57].

Despite being multifaceted, PRAMS was cited to possess elements that were simple in design. These elements included case definitions that were easy to apply and well understood at all levels, single level of reporting to CDC, standardized electronic and paper-based tools, integration with other data sources, and an established protocol. Nine stakeholders described the PRAMS system as simple. These stakeholders did not believe PRAMS was any more complex than other comparable surveillance systems. Taking all study data into consideration, this study labeled the PRAMS surveillance system as complex in accordance with the majority of stakeholders and the evidence presented in the document review. Appendix 23 details the key themes for simplicity.

5.2. Flexibility – Strength

A flexible public health surveillance system can adopt to changing information needs or operating conditions and can accommodate new health-related events and changes in case definitions. Two thirds of stakeholders agreed that PRAMS was a flexible surveillance system capable of addressing emergent and local health issues in the maternal and child health (MCH) community. This finding supported the Shulman (2018) study that found PRAMS to be a versatile system[10]. The utilization of supplements was frequently cited as a useful feature of the system to augment and customize the questionnaire to meet unique state objectives and data needs. Stakeholders reported that during past public health emergencies (i.e. the Zika virus and the opioid epidemic), PRAMS adapted its questionnaire to solicit information from respondents on how these emergencies were impacting the MCH community. More recently, PRAMS modified its questionnaire in response to the Coronavirus pandemic and adopted the COVID-19 Supplement, indicating its continued nimbleness to respond to new demands that may impact pregnancy risk[58]. To date, supplements have been developed for a variety of topics including family history of cancer, Zika virus, marijuana, prescription drug use and disaster preparedness[10].

For other health-related indicators of interest, the PRAMS system permitted participating sites to add questions to their surveys while keeping enough uniformity to allow for state-to-state comparisons. Tailoring survey content and administration strategies to meet the unique needs of states was identified by Ghandour (2018) as a chief strength of the PRAMS system[23]. In designing their surveys, states could choose from a library of standard questions or develop their own questions to address state priority topics[10]. The flexibility around the selection of content was complemented by the ability of each state to tailor selected aspects of survey administration, ranging from the application of state-specific branding to the use of targeted incentives[23]. Both the document review and the stakeholder interviews revealed that participating sites were also able to select stratification plans according to their own priorities to estimate prevalence data in their respective areas. Study findings indicated that periodic evaluations and process improvement strategies were built into the PRAMS project design, allowing the surveillance system to be adaptable and agile. As maternal and child health topics changed and evolved, the PRAMS questionnaire was updated every three to five years to reflect new topics and/or modify existing issues[56]. PRAMS also partnered with external organizations and modified its data collection methodology to contribute to program evaluations of community-based maternal and child health programs (i.e. Supplemental Nutrition Program for Women, Infants and Children and Healthy Start)[10 59].

While the overall PRAMS program was identified as being flexible, many stakeholders noted that there was room for further improvement. Three stakeholders mentioned the effort, cost and time involved with adding supplemental questions were barriers to rapid implementation and timely data. Forty percent of stakeholders argued that PRAMS' technology was rigid and in need of modernization. The lack of a web-based survey was a primary concern for stakeholders. A few

participating sites stated they joined a pilot for PRAMS web implementation a few years ago, but the web-based questionnaire was never executed across all sites. Although mailings were the primary mode of data collection, it was viewed by some as archaic and restrictive. Participating sites were interested in exploring new ways to solicit feedback from mothers, many of whom are millennials. Texts, emails, QR codes and web-based surveys were mentioned as new modes that can strengthen PRAMS' nimbleness and flexibility. Overall, study findings evidenced flexibility as being an important characteristic of the PRAMS surveillance system. Appendix 24 details the key themes for flexibility.

5.3. Data Quality – Strength

Data quality in a surveillance system is examined by the completeness and validity of the data collected by the system. It was evident through study findings that PRAMS had a reputation of providing valid and reliable data. Over 80% of stakeholders agreed that PRAMS should be acknowledged for its ability to maintain high data quality and for its continued diligence in enhancing the validity of data collected by the surveillance system. Many stakeholders expressed confidence in the quality of the PRAMS data and took pride in it. Others discussed the evaluation, monitoring and quality control efforts that were built into routine activities and procedures. Some examples included pretesting PRAMS questions, range checks, data entry verifications, monitoring of response rates, frequent program evaluations, adequate sample sizes, IRB approvals and staff trainings. PRAMS staff members were committed and ensured proper adherence to operational and data collection procedures that are essential to the quality and consistency of PRAMS surveillance data. Additionally, the PRAMS protocol required that questionnaires less than 75% complete were to be followed up by telephone to avoid missing data and to maintain high data quality[56].

One stakeholder mentioned the declining response rate as a concern for data validity. To improve declining response rates and validity of the data collected, the PRAMS protocol encouraged participating sites to periodically evaluate data collection methods, stratum-specific response rates, and characteristics of non-respondents. Despite this concern, PRAMS had a reputation of high reliability and validity that preceded the surveillance system and shared similar findings when compared with other national surveys, such as the National Maternal and Infant Health Survey and the National Survey of Family Growth[14]. The aforementioned measures altogether provided sufficient evidence for assessing data quality and suggested that PRAMS was able to maintain data of high quality. Appendix 25 details the key themes for data quality.

5.4. Acceptability – Strength

A surveillance system with acceptability encompasses the willingness of persons to participate in the system. There was consensus among stakeholders that PRAMS had high acceptability and willingness of persons to participate in the surveillance system. While considering points of interaction between the surveillance system and its participants, it was observed that PRAMS had acceptability among four key stakeholder groups: (1) mothers responding to the survey, (2) sites participating in the program, (3) PRAMS staff, and (4) PRAMS data users. The study observed that most mothers were genuinely willing to participate in PRAMS to share their pregnancy experiences, demonstrated by their willingness to complete the questionnaire. Response rates were the strongest indicators of acceptability, as it was assumed that if a mother completed the survey, then she consented to participating in the program[60]. Stakeholder interview responses to acceptability were influenced by the response rates in their states. States with response rates above the minimum threshold found that mothers were very willing to participate in the program with minimal incentivizing. States that struggled to meet the response rate threshold or had low response

rates in a specific stratum, questioned the acceptability of the system and indicated the increased need for follow-ups, rewards and incentives. PRAMS' utilization of rewards and incentives as a recruitment strategy was identified as a leading factor that influenced the acceptability of the system. In general, stakeholders witnessed that participants were interested in providing data to the PRAMS surveillance system so that findings could be translated into public health action benefiting maternal and infant health in their states.

The number of participating sites across the United States increased considerably since PRAMS' 1987 debut, from 6 to 50 participating sites[7]. This growth in site participation substantiated the acceptability of the surveillance system among state-level public health departments. Participating sites, as well as PRAMS staff, sincerely believed in the public health importance of PRAMS and the data it provided. A few stakeholders noted increased buy-in among PRAMS staff to successfully manage the surveillance system, as well as how favorable the PRAMS program was among external users. PRAMS had an extensive list of data users that were interested in the indicators captured by the system and were willing to collaborate with PRAMS. These data users included researchers, state and local governments, policymakers, public health administrators, health organizations, public health agencies and organizations, and community providers[6 61]. PRAMS data was highly requested by these end users because they accepted the data and had buy-in to how the data was collected.

PRAMS' public health importance was demonstrated by its ability to serve as a state-specific data source for identifying trends in maternal and infant health. Its acceptability was influenced by its extensive range of societal benefits, including the demonstrated utility of the system to inform national- and state-level policy and programming[61]. Multiple states reported using the PRAMS data internally to support and monitor yearly priorities, to determine resources and funding for

different counties, and to inform the Title V Block Grant comprehensive needs assessment. For example, Alabama used PRAMS survey responses to identify groups of women at high risk for infant health problems and to measure progress in reducing negative pregnancy outcomes[62]. New York City used PRAMS findings to enhance their understanding of maternal behaviors that are important for good reproductive outcomes and infant health, to develop and evaluate programs to improve maternal and infant health, and to inform policy development relevant to reproductive health[63]. Several participating states reported sharing their PRAMS data externally with policymakers to support decision making and legislative proposals. These states were very interested in sharing PRAMS data with legislators to ensure that decisions impacting the MCH community were data driven. One state mentioned using PRAMS data to develop a maternal mental health report to present to their local legislation. Another state partnered with their governor's office that was interested in the experiences of violence during pregnancy. PRAMS' public health influence, coupled with the fact that all survey responses are kept strictly confidential, contributed to its acceptability among participants. Appendix 26 details the key themes for acceptability.

5.5. Sensitivity – Strength

A surveillance system with satisfactory sensitivity is able to estimate the proportion of the total number of events in the population under surveillance. For PRAMS, this meant sensitivity was the proportion of mothers or infants identified with the condition of interest who were detected by the surveillance system. Information gathered from the document review and stakeholder interviews offered evidence supporting favorable sensitivity for the PRAMS surveillance system despite some limitations. The document review portrayed PRAMS as an ongoing system capable of identifying a wide range of risk factors, providing reliable prevalence estimates, tracking health indicators

over time, and monitoring health behavior and practices[6]. This description alluded to a system that was sensitive enough to consistently detect changes and patterns over time in the MCH community. Approximately 85% of stakeholders believed that PRAMS can estimate the proportion of the total number of cases in the population under surveillance. Most stakeholders believed in the validity of the system and its ability to collect information from subgroups. Many expressed confidence in CDC's thorough weighing process to validate data and account for bias estimates that may occur during the sampling process. The weighing process was consistent across all participating sites, providing assurance in the prevalence estimates that were generated. A stakeholder stated that PRAMS was *"as good as you can get for population level surveillance"*. Two stakeholders disagreed with the group consensus and believed that PRAMS provided board snapshots but could not be extrapolated to represent the entire population in their states.

PRAMS' sensitivity was influenced by the willingness of respondents to accurately report their behaviors and experiences, the ability of respondents to understand the questions on the survey and correctly identify their status, and the validation of the data collected from the surveillance system. The document review found that the PRAMS system was subjected to self-reporting biases (i.e. social desirability bias and recall bias), which could lead to inaccurate prevalence estimates[14]. Robbins (2009) observed that negative behaviors (i.e. smoking, drinking or exposure to secondhand smoke) may be underestimated and positive behaviors (i.e. having postpartum checkups and current use of contraception) may be overestimated on the PRAMS survey[26]. These findings were confirmed by a few stakeholders that identified under-reporting of sensitive issues as a limitation to the willingness to accurately report behaviors. Despite this concern, general findings from the document review and stakeholder interviews pointed to PRAMS's ability to

provide participating sites with truthful estimates of their population, confirming findings of other research studies[64 65].

All stakeholders agreed that respondents were capable of understanding the PRAMS survey. Some attributed the clarity of the survey to CDC's field testing and acknowledged the careful construction and design of the survey. Several stakeholders shared that very few respondents had questions regarding the survey or needed further clarification. Regarding data validation, the PRAMS protocol included processes to verify that the survey was completed by the intended audience, such as confirmation of important information (i.e. date of birth of mothers and infants). However, the protocol did not include processes to validate self-reported responses for accuracy. This was identified as an area of improvement for the surveillance system. Appendix 27 details the key themes for sensitivity.

5.6. Positive Predictive Value (PPV) – Limitation

A surveillance system with satisfactory positive predictive value (PVP) has a high proportion of reported cases confirmed to have the health-related event under surveillance. For PRAMS, PVP described the performance of the surveillance system to accurately identify true cases of pregnancy-related risk indicators. This study observed positive predictive value as a significant shortcoming of the PRAMS system due to its limited ability to confirm cases reported through the surveillance system. Stakeholder interviews revealed that PRAMS did not have a standard process for identifying false positives and confirming true positive cases classified by respondent's self-reports. Such a process would require case investigations prompted by information obtained by the surveillance system. It was evident from study findings that PRAMS was not designed to formally conduct case investigations to confirm individual self-reported data.

To address the absence of case investigations, some participating sites developed separate strategies to validate subsets of their PRAMS data. These strategies included linking PRAMS data to other comparable data sources, forming focus groups and confirming PRAMS data patterns with local stakeholders in the community. The strategies used among participating sites varied depending on the topics of interest under investigation and the availability of data sources, leading to patchwork efforts to confirm data reported through the PRAMS system. There was consensus among stakeholders that medical records and birth certificates were the most common data sources used to validate PRAMS data. Prior research studies comparing PRAMS data to birth certificates and medical records confirmed accounts from stakeholders[64 65 66]. Several stakeholders described the limitations of these data sources and agreed that there was no perfect gold standard for comparison. Finally, a few stakeholders reported that their sites did not conduct any case investigation activities to substantiate PRAMS self-reports. The lack of case investigations signified a probability of false positive reports within the PRAMS system, especially for health indicators that were less common in the population[65]. Appendix 28 details the key themes for positive predictive value.

5.7. Representativeness – Strength

A surveillance system that is representative can accurately describe the occurrence of a health-related event over time and its distribution in the population by person and place. PRAMS' representativeness was examined using the systematic sample of mothers who recently gave birth to a live infant in a given state. Since PRAMS was a state-wide surveillance system that used birth files as its sampling frame, there was confidence in the system's ability to capture a representative sample of all live births in the population, reflecting the total population of interest[67]. There was strong consensus among stakeholders that PRAMS can generalize findings to represent their

state's population. Many were confident in PRAMS ability to monitor trends over time in generalizable ways and in using the data to draw meaningful conclusions about the population. One stakeholder mentioned that for homogenous states (i.e. states with a high percentage of residents that identify as non-Hispanic White), PRAMS is only generalizable for that percentage of the population. These less diverse states often struggle to get adequate samples from non-White participants, which impacts the ability to accurately measure various population health metrics by race/ethnicity and the disclosure of that data.

Document review findings demonstrated that the PRAMS surveillance system used stratified sampling and considered numerous statistical measures of population variables (i.e. age, race, ethnicity, education, geographic area and year of birth)[10]. These variables related to person, place and time, and were shown to accurately reflect the characteristics of the population under surveillance. Inferences about stratums required some subpopulations to be sampled at a higher rate than other subpopulations[68]. The main advantage of stratified sampling was that it permitted separate estimates of subpopulations that may not represent a large portion of a state's overall population[68]. Furthermore, the PRAMS system had established itself as being a reputable source for pregnancy-related health indicators because of its ability to describe events at appropriate points over the broad pregnancy continuum (i.e. before pregnancy, during pregnancy and after delivery)[23].

An important component of evaluating the representativeness of the surveillance system was the identification of population subgroups that were systematically excluded from the sample. PRAMS systematically excluded all pregnancies that did not result in a live born infant (i.e. stillbirths and induced or spontaneous abortions) and consequently, did not reflect the entire population of pregnant women within the state[14]. Additionally, PRAMS data only reflected births

within a given state and findings could not be generalized to other states[14]. PRAMS exclusion criteria allowed for a more accurate projection of prevalence estimates in the target population, mothers with live births. In addition, errors and biases could be introduced into the PRAMS system at any stage. For PRAMS, differential bias was a possibility as some subgroups were more likely to not respond to the survey or have missing/inaccurate data compared to other groups[69]. To address this potential problem, CDC PRAMS applied non-response weighted adjustments that rested on the assumption that, within a stratum/subgroup, the average of the answers of the respondents was the same as the average of the answers of the non-respondents[69]. When interpreting PRAMS findings, it was important to consider whether the data may be subject to any exclusions and biases and how these may result in misleading conclusions about the health-related event under surveillance[69]. Appendix 29 details the key themes for representativeness.

5.8. Timeliness – Limitation

The timeliness of a surveillance system takes into consideration the speed between steps in the system and the availability of information emerging from the system to influence control of the health-related event of interest. For PRAMS, timeliness meant the speed between case occurrence and data collection, the speed between data collection and result reporting, and the timely use of data to promote maternal and infant health through control efforts, prevention of continued exposure, program planning and policy development. According to the document review, the PRAMS system was timely regarding its recruitment efforts of mothers two to four months after delivery[8]. This time interval was sufficient for the objective of the system to capture data on the preconception, pregnancy and postpartum periods.

Conversely, PRAMS' speed between data collection and reporting was identified as prolonged and lengthy. Most stakeholders cited timeliness as one of the biggest complaints data users had regarding the PRAMS surveillance system. There was general consensus that PRAMS's level of timeliness was not satisfactory for effective control effects, prevention and program planning. All stakeholders agreed that more timely data would be very helpful for end users interested in PRAMS data, increasing the utilization of actionable data. Study findings indicated that the timeframe for making PRAMS data available to states was approximately 6 to 12 months after the completion of data collection in a given year[10]. A one-year lag time after the close of data collection was identified as satisfactory for an annual surveillance system; however, lag times greater than a year were deemed as unacceptable. Some states reported waiting up to two years for PRAMS data of a specific birth year. A few stakeholders mentioned that CDC had made efforts to improve turnaround time for participating sites and getting weighted data back quicker. For example, this year, some participating sites received 2019 weighted data sets as early as six months after the close of the surveillance period (June 2020).

Many stakeholders described the various steps of the PRAMS data collection and weighting processes and stated that they understood the necessary time intervals of the yearly surveillance system. There was a general belief that the faster a state submitted their final data to CDC, the quicker the turnaround time will be for their weighted data. This was confirmed by the PRAMS protocol that stated the time frame for analysis data sets were dependent on the receipt of cleaned data files and final birth files from the states[70]. States reported doing their best to control what they can to expediate the data process (i.e. submitting annual birth files, expiring and verifying batches, etc.). For many, it was a balance of having more timely data and maintaining the integrity of the PRAMS protocol to collect valid, representative data.

Communicating delays of PRAMS data to end users was a concern for stakeholders. End users were requesting more updated data to respond to emerging issues (i.e. the Coronavirus pandemic and how COVID-19 was affecting the maternal and child health population), as well as plan programs and policies. Newly developing issues in the maternal and child health population often require rapid responses. Delays in PRAMS information may obstruct timely implementation of necessary interventions or lead to control efforts that are no longer pertinent to the MCH population at the time of implementation. Overall, improvements in timeliness of data was cited as an area of improvement for the PRAMS surveillance system. Appendix 30 details the key themes for timeliness.

5.9. Stability – Strength

A stable surveillance system is reliable and available, meaning it can collect, manage and provide data properly without failure and be operational when it is needed. PRAM's stability was measured by examining the longevity of the program, the accessibility of data, the availability of dedicated resources and the frequency of downtimes of the system's computer program (PIDS). While investigating these measures, the study findings illustrated the stable performance of the PRAMS system, indicating very few threats to its ongoing operations. PRAMS had proven itself to be an ongoing surveillance system capable of tracking trends in maternal and infant health indicators over time and monitoring health behaviors and practices. Since its inception in 1987, PRAMS has been a valuable contributor to the MCH community and a national source for state-specific MCH data, some of which were not available from any other data sources[10]. It was evident that a surveillance system that has been in existence for over three decades was sustainable and durable. Many end users trusted the PRAMS system because of its reputation of being available and reliable. PRAMS' continual data collection suggested the constant flow of information in and out

of the surveillance system. The dissemination and availability of PRAMS data was a main objective of the surveillance system and was evident by the various formats used for data distribution (i.e. reports, presentations, factsheets, data files, etc.)[69 71]. Study findings demonstrated that the PRAMS system was designed to account for broad data dissemination that would lead to public health action.

The presence of dedicated resources was further evidence of PRAMS' stability because it provided the infrastructure needed to sustain the viability of the surveillance system. Assigning dedicated staff to the PRAMS program guaranteed a permanent and committed workforce to support the system. Adequate funding by CDC and local state departments was cited by many stakeholders as a critical component for guaranteeing the stability and longevity of the surveillance system. However, several stakeholders reported that the funding received from CDC was not enough to operate the full PRAMS system and that supplemental funding was needed.

Many stakeholders reported feeling confident about the stability of the surveillance system and that its processes and procedures have remained consistent over time. There was general consensus that the PRAMS system functioned as designed and experienced very few system downtimes. The scarcity of scheduled and unscheduled downtimes indicated that the system was regularly operational when it was needed. When downtimes occurred, PRAMS was able to continue operations manually to limit the impact to data collection and management. Appendix 31 details the key themes for stability.

Discussion

This research study was the first study to evaluate the Pregnancy Risk Assessment Monitoring System (PRAMS) against the nine public health surveillance system attributes described by the

U.S. CDC. Previous studies have looked at a few of PRAMS system attributes, including flexibility, timeliness, sensitivity and positive predictive value[23 64 65]. The utilization of the nine attributes provided the study with standards for assessing the system's performance, making the evaluation process more objective and comprehensive. The surveillance standards provided a rubric for thinking about the PRAMS system and all its various components. Furthermore, the study added to the existing research of public health surveillance system evaluations.

Qualitative Triangulation

The use of triangulation as a qualitative research strategy to test validity through the convergence of information from separate sources proved to be effective in evaluating the PRAMS surveillance system. The document review provided explicit information about the PRAMS program, design, processes and outcome measures. It also provided a great deal of evidence regarding PRAMS' performance in the nine public health surveillance system attributes. Of all the attributes, the document review offered the greatest detail for the following six attributes: simplicity, flexibility, data quality, acceptability, representativeness and timeliness. After reviewing approximately 50 documents, new information was no longer extracted from the documents, signifying data saturation.

The stakeholder interview was an insightful technique for increasing understanding of the PRAMS system by exploring system attributes in greater depth. The interviews focused on the remaining three attributes that needed more evidence than what was provided by the document review: sensitivity, positive predictive value and stability. It also validated the document review findings for all nine system attributes. The benefit of the stakeholder interview was that it elicited rich information about experiences with PRAMS and perspectives from individuals closest to the

program. After interviewing approximately 16 stakeholders, data saturation was reached. Coding, converging and analyzing the document review texts and stakeholder interview transcriptions uncovered sufficient evidence to effectively evaluate the PRAMS surveillance system.

Information collected from the document review and stakeholder interviews revealed assorted, yet complementary features of the PRAMS surveillance system. Three key observations were noted from the convergence of the document review and the stakeholder interviews. The first was that the findings from the document review and the stakeholder interviews showed consistencies between the two sources. In other words, the interviews were able to support findings initially found in the document review. For example, both sources described the intricate details of the PRAMS data collection methodology, explaining the recruitment of participants, collection of survey responses via mail and telephone, data entry verification and submission of annual birth files to CDC for final analysis. Another example was that both sources displayed the trust participating sites and end users had in the surveillance system to provide valid and reliable data on maternal and infant health indicators.

Second, the stakeholder interviews were able to shed light on areas undiscovered by the document review. For example, the document review revealed that PRAMS was a mixed-mode surveillance system and that participating sites were using mail as the primary mode of data collection, followed by telephone follow-ups. The stakeholder interviews exposed the concept of a web-based survey, possibly converting PRAMS into a tri-mode system. The potential for implementing a web-based survey was first examined a few years ago when selected states participated in a web implementation pilot. Findings from the interviews disclosed that the web survey was never put into practice following the pilot. Reasons for the lack of web implementation could be programming issues, staffing and funding deficiencies, and competing priorities at CDC.

Third, the stakeholder interviews were able to provide updates to outdated information found in the document review. For example, findings from the document review illustrated that there was typically a two-year window from a given birth year to when surveillance data was released for that year (i.e. data from 2018 births was released in 2020). Under the current protocol, weighted data from CDC was available to participating sites approximately 6-12 months after the completion of data collection in a given year[10]. Findings from the stakeholder interviews confirmed the timing variability of surveillance data for a given year. It also provided timing updates for data received in recent years. There were several stakeholders that reported having to wait the full two years for data in the past, and that in recent years, CDC had improved their turnaround time to less than two years. The most recent 2019 birth year was received in less than six months for some states after the completion of data collection (i.e. data from 2019 births was completed in June 2020 and released at the end of 2020). Recent updates in the reduced turnaround were noted by many stakeholders and proved to be valuable information for assessing PRAMS' timeliness attribute.

PRAMS Evaluation Across Attributes

The Pregnancy Risk Assessment Monitoring System was found to perform well on the majority of system attributes, signifying PRAMS to be an effective and useful surveillance system. Study findings proved the PRAMS system to be flexible to modification and accommodating to changes in the MCH community. The system reported good quality data, which was a direct result of the quality control measures embedded into the system's infrastructure. PRAMS was widely accepted by persons and organizations that participated in the surveillance system and has been adopted by 94% of U.S. states. Overall, the system collected data that was representative of mothers who delivered a live birth infant within a given state and accounted for subpopulations of interest (i.e. race, ethnicity, age, education and low birthweight). Stakeholders attested to PRAMS's sensitivity

and its ability to detect pregnancy risk issues and to capture relevant information on topics related to maternal and infant health outcomes. Finally, PRAMS was an established system with permanence and committed resources that ensured its stability and future continuity.

Study findings found the PRAMS system to be slightly more complex than it needed to be to meet the surveillance objectives. This may be due to the dual modes of data collection (i.e. mail and telephone), as well as multiple components of the system that occur simultaneously to one another (i.e. mailings, follow-up attempts, batching, etc.). These components added layers of complexity to the system, requiring constant and detailed effort from PRAMS staff to effectively operate the system. PRAMS' timeliness was slow as a result of the lengthy data collection and analysis process. Collecting survey responses by mail was not helpful for quick reporting. Additionally, submitting yearly files to CDC for weighting meant that some PRAMS data were not rapidly used as actionable data as soon as they were collected and had to be saved to be included in the yearly analysis process. PRAMS data was not very quick to meet the objectives of the system and its end users. Positive predictive value was low as a direct result of the lack of case investigations. PRAMS' low positive predictive value meant an increased possibility of the system to falsely identify behaviors and experiences associated with pregnancy risk. However, since PRAMS was designed to identify groups of women and infants at high risk for health problems and not to identify individual cases for treatment or follow up, having a low PPV may be acceptable to meet the population-based surveillance objectives.

It was difficult to determine whether the study's findings were consistent with other published reports, given the little evidence of this work in the literature. Conducting a search in PubMed for PRAMS evaluation revealed 67 publications. Only three publications provided relevant context for comparison. Ghandour (2018) highlighted flexibility has being a strength of the PRAMS

system and timeliness as an area of possible growth[23]. Ahluwalia (2013) identified high sensitivity and PPV for three health related indicators – WIC participation during pregnancy, delivery payment and breastfeeding initiation[64]. Dietz (2014) found that measures of sensitivity and PPV varied with PPV preforming poorly for four health related indicators – pregnancy history, complications during pregnancy, health care utilization and infant indicators[65]. Findings from study aim 1 were consistent with these previously published reports regarding timeliness, flexibility and sensitivity. This study contradicted Ahluwalia (2013) and identified inadequate performance of PPV in the PRAMS system. To adequately assess PRAMS' PPV, CDC guidelines suggest quantitative measurements that include the collection of data usually external to the system[19]. Further evaluations of PRAMS' PPV and sensitivity will be conducted in study aim 2.

In the case of PRAMS, it was worth noting that the surveillance system did not have to perform well in all nine attributes to be considered a useful and effective system. This was consistent with surveillance system research that noted all attributes cannot be at the highest level at the same time[72]. A surveillance system evaluation should emphasize those attributes that are of the highest priority for a given system which is influenced by the system's purpose, objectives, scope and methods. Given the study findings, it was presumed that attributes most important to the PRAMS surveillance system were the attributes with favorable performances: flexibility, data quality, acceptability, sensitivity, representativeness and stability.

Interdependency of Attributes

Although the nine surveillance system attributes were evaluated individually, they were not independent of each other. Most of the attributes were interdependent, meaning one attribute had impact on another attribute. There were some attributes that complemented and supported each

other. One example was PPV, sensitivity and data quality. Although PRAMS' PPV and sensitivity provided different perspectives of how well the system was operating, together they portrayed the ability of the system to accuracy detect health-related events and classify respondents. Subsequently, improving PPV and sensitivity will positively impact the accuracy and quality of data captured by the surveillance system.

A second example was data quality, acceptability and representativeness. PRAMS' high data quality allowed the system to be accepted by those who participated in it, as well as provided confidence that the system can accurately represent the health events and population under surveillance. Equally, PRAMS' high participant acceptability allowed for data completeness and less missing data, leading to increased quality.

A third example was simplicity and timeliness. Increasing the simplicity of a surveillance system would require having fewer processes and simpler workflows, resulting in less time spent on maintaining the system and improved timeliness. For a system with low simplicity such as PRAMS which involves several simultaneous processes, additional time was needed for proper adherence to data collection and management protocols, subsequently weakening timeliness of data dissemination.

Conversely, there were a few attributes that were competing and inversely related. Efforts to strengthen certain attributes detracted and weakened others. One example was simplicity, sensitivity and positive predictive value. Efforts to increase sensitivity and PPV may increase the complexity of the surveillance system, adversely affecting simplicity. For a system like PRAMS with relatively low PPV, strengthen PPV would require additional processes and resources to

confirm cases reported through the system. It may also negatively affect the acceptability and timeliness of the surveillance system.

Limitations

This assessment of PRAMS as a public health surveillance system has several limitations to take into consideration. First, it was a qualitative research study that used subjective measures to evaluate PRAMS' surveillance system attributes. The quality of the research was heavily dependent on the individual skills of the researcher and was subjected to the researcher's personal biases and idiosyncrasies. Furthermore, the stakeholder interviews were open-ended, allowing participants to express their preconceptions and to have more control over the content of the data collection. The study was not able to objectively verify all data used for the qualitative analysis.

A second limitation was that the study only recruited individuals that worked directly with the PRAMS system to participate in the stakeholder interviews. There were other stakeholder groups that interact with the PRAMS surveillance system that could have provided valuable information to the research study. Other stakeholder groups included mothers that responded to the PRAMS survey, researchers that used PRAMS data to investigate pregnancy risk factors, policy makers that used PRAMS data to improve policy decisions, and federal PRAMS stakeholders. Although these stakeholder groups were not included in the study, the study did include individuals that operate the PRAMS system and use the data for surveillance.

A third limitation was the sources of data for the document review. The study data contained information gathered from documents that were publicly available online. Documents that were not accessible to the general public were not included in the study data. Additionally, due to the

immense number of documents available online, documents that provided evidence regarding PRAMS' performance were selected at the discretion of the researcher.

A final limitation was the limited generalizability of the study findings. Although the study successfully evaluated the Pregnancy Risk Assessment Monitoring System, its findings may not be applicable to other public health surveillance systems. Surveillance systems vary in methods, scope, purposes and objectives, resulting in varying attribute priorities. Hence, individual surveillance systems require separate evaluations that consider attributes that are most important for the objectives of the system. A surveillance system that is similar to PRAMS (i.e. CDC's Behavioral Risk Factor Surveillance System [BRFSS]) may adopt a few of the study findings that are appropriate for the given system. Study findings can be generalized to all sites participating in the PRAMS surveillance system.

Recommendations

The study recommends several modifications and considerations that can improve PRAMS' surveillance system attributes. It should be noted that efforts to improve an attribute may worsen another and that balance of personnel, resources and cost should be considered for each recommendation. Portions of the recommendations were discussed by key stakeholders during interviews, and others originated from the study's researcher.

Stakeholders' Recommendations

To address simplicity, timeliness and acceptability, the first recommendation is the implementation of a PRAMS web-based survey. Stakeholders were extremely vocal and passionate about this recommendation, signifying the importance of a web-based survey to end users.

> Stakeholder Quote: *"We will be looking forward to adopting a web-based modality because we anticipate that would take off a large amount of the burden of individuals who choose to participate by mail. And so, there would be less of a need to prepare mailers and do data entry once those hard copies came in. So, there's quite a lot of benefits to having that web-based survey."*

It is time for CDC PRAMS to utilize modern technology to reach the next generation of mothers that stand out for their use of digital technology. Studies have shown that electronic surveillance systems have evolved rapidly over recent years[73] [74]. It is a tool that creates opportunities for automation of data collection and the potential to decrease the time spent on conducting manual surveillance. If PRAMS adopts an electronic survey, the web-based survey could promote participation among mothers, significantly reduce PRAMS' manual processes, promote timeliness of actionable data, and allow PRAMS to remain competitive with other surveillance systems during a time of declining response rates to unsolicited surveys.

To strengthen flexibility, timeliness and stability, the second recommendation is an increase of dedicated CDC resources to support the PRAMS surveillance system.

> Stakeholder Quote: *"We have nobody that we can call if our phone interviewers are working on the weekend…There's no support line. We have to wait until the weekday. The resources are not there to be completely comprehensive. I think [CDC] is strapped for resources and there is definitely room for improvement. Should we ever have funding to be able to add to the team and do more, that could be useful to states in these off hours. That's where we're kind of lacking."*

Study findings clearly emphasized the need for dedicated and committed personnel to effectively support ongoing PRAMS operations. An increase in CDC's PRAMS staff would enhance the existing support offered to participating sites in several ways. First, it could expand the availability of CDC staff during off-hours (i.e. evening and weekends) to troubleshoot issues with the PRAMS system. This would greatly benefit participating sites residing in different time zones (i.e. Alaska and Hawaii) by providing them with greater access to CDC resources located on the east coast of the United States. Second, it could assist with the speed of processing and weighing data for all participating sites, resulting in quicker turnaround times for PRAMS data. Third, additional staffing may be required for successful implementation of a web-based PRAMS survey.

To promote acceptability and representativeness, the third recommendation is to conduct a non-response analysis to better understand why some individuals are not completing the PRAMS survey.

> Stakeholder Quote: *"We haven't done a non-response analysis to see for people who don't complete the survey, are we able to get in touch with them, but they're not choosing to complete the survey versus are we not reaching them in the first place."*

There are a number of reasons why individuals may not complete the PRAMS survey, including inaccurate contact information, competing priorities, lack of motivation, language barriers, etc. If participating PRAMS sites had a better understanding of barriers leading to survey non-response, they would be better positioned to rectify recruitment oversights, if applicable, and develop tailored interventions to alleviate participation burden, with the goal of increasing participation in their geographic areas.

Researcher's Recommendations

To enhance the stability and acceptability of the surveillance system, the fourth recommendation is the implementation of a new online database where diverse user groups can retrieve PRAMS data. CDC PRAMStat was an online data query system that used to be available to the general public and accessible via the CDC PRAMS website for quick analyses of most core PRAMS indicators. The PRAMStat system was replaced by the PRAMS Data Portal for PRAMS data from 2000-2011. Both systems are no longer available online for the general public. CDC PRAMS should strongly consider reestablishing a data query system that assures timely data in a format accessible by data users. This open data platform will allow users to download selected PRAMS data as necessary and manipulate the data to best suit their needs.

To strengthen sensitivity, positive predictive value and data quality, the fifth recommendation is to require case investigations for a feasible percentage of the sample. The PRAMS protocol incorporates data entry verification on a minimum of 10% of mail surveys and monitoring of 10% of all telephone calls to make sure the survey is properly administered, and responses are properly recorded. Quality control measures should extend to verifying the accuracy of responses through case investigations. Participating sites should be able to select health indicators for case investigations based on local priorities and their ability to validate survey responses, including the availability of comparable data sources external to the PRAMS system. This will require additional processes and resources to investigate respondents that self-reported as having a health-related event of interest.

To advance stability, the sixth recommendation is to incorporate standard downtime procedures into the PRAMS surveillance system. The purpose of having downtime procedures is to maintain

the integrity of PRAMS data and processes, and to ensure the continuation of the surveillance system during the absence of its electronic system, PIDS. Although downtimes of the PIDS are infrequent, it is important for the surveillance system to have built-in redundancies to account for these downtimes. Manual downtime procedures that are standardized across all participating sites can promote resilience and strengthen the stability of the surveillance system.

Chapter 6: Methods – Study Aim 2

Research Question

The second research question guiding this dissertation is: How valid and reliable are PRAMS self-reported health indicators, specifically selected proximate determinates of preterm birth that are self-reported on the PRAMS Phase 8 questionnaire?

Study Design

This study was a secondary analysis of retrospective PRAMS data. Using PRAMS' most recent survey questionnaire (Phase 8), the study identified key health indicators that were evidenced-based and proven to be associated with preterm births. These key health indicators were then matched with birth certificate files. Study variables were selected if indicators were included in the self-reported PRAMS questionnaire, as well as in birth certificate files. Information from birth certificates was used as the reference standard (true positives and true negatives). This study selected Maryland as the sample state and linked Maryland's PRAMS data to the state's birth certificate files for comparability of responses for selected health indicators. The study did not have a control group.

Study Setting

For the purpose of this study, the study setting was Maryland. The state of Maryland has 23 counties and 1 independent city (Baltimore City), for a total of 24 main local jurisdictions. Maryland was selected because maternal and child health continues to be a public health concern for the state. In 2019, Maryland was ranked 33rd among all U.S. states in preterm births, meaning that 64% of states ranked higher than Maryland on the metric of preterm births[75]. Additionally,

Maryland was unique in that its preterm birth rate was consistently higher than the U.S. average, 10.5 deaths per 1,000 live births and 9.9 deaths per 1,000 live births, respectively in 2019 (Appendix 9)[76].

Additionally, Maryland had a demographically diverse population. According to the most recent U.S. Census, the racial composition of Maryland was[77]:

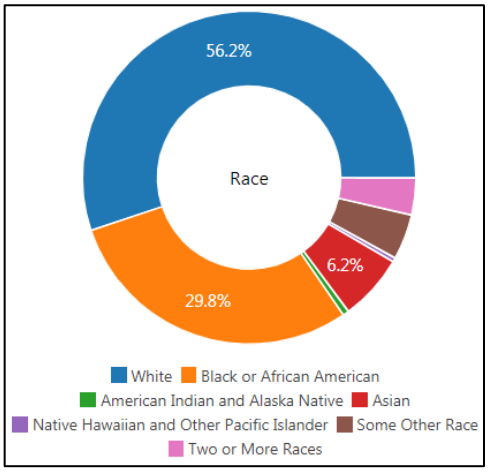
Table 7: Population by Race, Maryland

Race	Population	Percentage
White	3,343,000	55.54%
Black	1,799,098	29.89%
Asian	378,126	6.28%
Other Race	272,137	4.52%
Two or More Races	206,692	3.43%
American Indian and Alaska Native	16,762	0.28%
Native Hawaiian and Other Pacific Islander	3,034	0.05%

Source: World Population Review 2020

Figure 3 shows a pie chart summarizing the percent distribution by race in the state of Maryland[77]. Persons who self-report as Hispanic can be of any race and represented 10.1% of Maryland's total population[77].

Figure 3: Percent Distribution by Race, Maryland



Source: World Population Review 2020

Inclusion Criteria

PRAMS' population of interest includes all mothers who are residents of a given state and deliver a live-born infant in that state during the surveillance period. For this study, the inclusion criteria for eligible mothers are described below:

a. Maryland Resident – Only mothers that were residents of the state of Maryland were included in the study.

b. In-State Births – Only Maryland residents that delivered in the state of Maryland were included in the study. In-state births of non-residents and out-of-state births of residents were excluded from the study.

c. Live births – Mothers that give birth to a live infant were included in the study. Women eligible to participate were selected from live birth certificate files. The live birth certificate data allowed for the survey data to be weighed to reflect the total birth population[13]. By using birth certificate files, PRAMS excluded stillbirths, fetal deaths and induced abortions.

d. Completed PRAMS Survey and Birth Certificate – Mothers must have completed the PRAMS Phase 8 survey and have birth certificates that included the mother's last name. Infants whose birth certificates lacked the mother's last name were excluded because this information was crucial for follow-up.

e. Surveillance Period – Only mothers who gave birth in 2016 and 2017 were included in the study. Births in 2018 were excluded because Maryland did not meet CDC's response rate threshold in the 2018 surveillance year. During the data collection period of this study, data from 2019 births were not released by CDC.

Using this inclusion criterion, over 2,000 mothers were sent the PRAMS survey each year in Maryland.

Sources of Data

Data for study aim 2 was collected retrospectively and was provided by the Maryland Department of Health's Vital Statistics Administration (VSA). VSA managed the collection of PRAMS data, as well as birth certificate data. The data request was approved by the Institutional Review Board (IRB) of the Maryland Department of Health before data was released for study use.

PRAMS Sampling Plan

For PRAMS surveillance, women from some groups were sampled at a higher rate to ensure adequate data were available in smaller but higher risk populations[8]. This allowed states to make inferences about specific subpopulations and comparisons between subpopulations. For the state of Maryland, a stratified, random sample of approximately 200 live births was selected each month. The sample was stratified by maternal age (<35 years, ≥ 35 years) and infant birth weight (<2500 grams, ≥2500 grams)[13]. Consequently, mothers who were 35 years of age or older, or delivered a low-birthweight infant in Maryland (<2500grams) were over-sampled and a weighted factor was applied to the PRAMS data.

Nonresponse weighted adjustments were applied to compensate for the tendency of women having certain characteristics to respond at lower rates than women without those characteristics (i.e. race/ethnicity, being unmarried or of lower education). The rationale for applying nonresponse weights was the assumption that non-respondents would have provided similar answers to respondents' answers for the stratified category[8]. Maryland applied both sampling and nonresponsive adjustments factors to ensure the results were generalizable to the state's population

of women delivering live birth infants during the study period. For example, in 2017, 1,060 mothers completed the PRAMS questionnaire with a weighted response reflecting 64,204 mothers[78]. Table 8 presents the 2016 and 2017 weighted figures of number of births to mothers by race/ethnicity categories[78] [79].

Table 8: Weighted Figures by Race/Ethnicity in Maryland, 2016 and 2017

	2017		2016	
Race/Ethnicity	**# of births**	**% of births**	**# of births**	**% of births**
White non-Hispanic	26,779	41.7%	28,302	43.0%
Black non-Hispanic	19,403	30.2%	19,965	30.3%
Hispanic	10,854	16.9%	10,420	15.8%
Asian	4,840	7.5%	4,800	7.3%
Other/Mixed	2,123	3.3%	2,123	3.2%
Missing race/ethnicity	131	0.2%	150	0.2%
American Indian	74	0.1%	92	0.1%

Source: Maryland PRAMS Reports, 2016-2017 Births

Response Rate

PRAMS has a minimum overall response rate threshold policy for public data release. Table 9 displays Maryland's PRAMS weighted response rates from 2001 to 2017 and is color-coded by phase[80]. Although there has been a decline in the number of respondents and the response rates over time, Maryland has met the minimum overall response rate for the release of data set by CDC until 2018 when it did not meet the response rate threshold. Response rates are crucial to the quality of public health surveillance systems. Although weighted adjustments may not adequately compensate for low response rates, this assumption was justified for response rates greater than 50%[81]. Furthermore, Table 9 illustrates how survey responses are used to reflect the larger population of Maryland mothers using the weighted adjustments.

Table 9: PRAMS Response Rates for Maryland, 2001-2017

Phase	Year	# of Respondents	Weighted Response Rates	# of Mothers in Weighted Response
8	2017	1,060	57.2%	64,204
	2016	1,167	62.0%	65,852
7	2015*	1,288	65.1%	66,226
	2014	1,343	66.4%	66,635
	2013	1,305	64.9%	65,068
	2012†	945	65.1%	65,953
6	2011	1,466	65.0%	66,202
	2010	1,499	66.9%	66,794
	2009	1,583	69.3%	67,669
5	2008	1,713	73.4%	69,471
	2007§	1,673	70.4%	69,871
	2006	1,712	71.0%	69,014
	2005	1,359	>70%	55,609
	2004	1,617	73%	65,736
4	2003	1,627	73%	66,063
	2002	1,463	72%	64,292
	2001£	1,147	>70%	58,982

* 55% response rate threshold for data release by CDC begins

†60% response rate threshold for data release by CDC begins

§65% response rate threshold for data release by CDC begins

£70% response rate threshold for data release by CDC

Source: Maryland PRAMS Reports, 2001-2017 Births

Protection of Human Subjects

Study aim 2 is under the support of the Johns Hopkins' Institutional Review Board (IRB) study number 00013986, as well as by the Institutional Review Board (IRB) of the Maryland Department of Health. Both IRBs confirmed that identifiable information was excluded from the data provided to the study. There was no direct contact with human subjects. The research team took precautions to protect study data by using password protected devices and secured data storage.

Study Variables

While PRAMS had a comprehensive list of variables, not every variable was a predictor of preterm birth. Some variables are directly related to postpartum care and were excluded from the scope of this study. Table 10 lists the ten health indicators that were predictors of preterm birth and were found in the Maryland PRAMS Phase 8 questionnaire and Maryland birth certificate files.

Table 10: Study Variables, Study Aim 2

Health Indicator	PRAMS Question	PRAMS Variable	Birth Certificate Question	Birth Certificate Variable
1. Maternal Age	What is your date of birth?	MDOB_DAT	Maternal day of birth	DD_MDOB MM_MDOB YY4_MDOB
2. Maternal Nutrition – Mother's BMI	How tall are you without shoes? Just before you got pregnant with your new baby, how much did you weigh?	MOM_MTRS MOM_WT	Maternal height – Feet & Maternal height - Inches Maternal weight – Pre-pregnancy	MAT_HTFT MAT_HTIN MAT_PRWT
3. Maternal Health – Pregnancy Hypertension	During your most recent pregnancy, did you have any of the following health conditions: High blood pressure (that started during this pregnancy), pre-eclampsia or eclampsia?	MORB_BP8	Hypertension?	MM_HBP
4. Maternal Health – Gestational Diabetes	During your most recent pregnancy, did you have any of the following health conditions: Gestational diabetes (diabetes that started during this pregnancy)?	PG_GDB8	Gestational diabetes?	MM_DIAB
5. Maternal Health Insurance	What kind of health insurance do you have?	PP8_HCEX PP8_PAR PP8_WORK PP_MEDIC PP_MILIT PP_NONE PP_OTH PP_TYPE	Method of payment	PAY
6. Reproductive History – Previous Live Births	Before you got pregnant with your new baby, did you ever have any other babies who were born alive?	PREV_LB	No. of prev. live birth	PRE_LB
7. Reproductive History – Previous	Did you ever have a baby by cesarean delivery or c-section?	DEL_PREV	Repeated C-section	DEL_RCS

Cesarean Delivery				
8. Cigarette Smoking – Pre-pregnancy	In the 3 months before you got pregnant, how many cigarettes did you smoke on an average day?	SMK6_3B	No. of cigarettes smoked - prior to pregnancy	CIG_PRIOR
9. Cigarette Smoking – Last 3 months of pregnancy	In the last 3 months of your pregnancy, how many cigarettes did you smoke on an average day?	SMK6_3L	No. of cigarettes smoked - 3rd trimester	CIG_3TRI
10. Prenatal Care	How many weeks or months pregnant were you when you had your first visit for prenatal care?	PNC_WKS PCV_DATE BC_GEST IDOB_MTH IDOB_YR4	Date of first prenatal care visit Obstetric estimation of gestation Infant date of birth	DD_PCV MM_PCV YY4_PCV GEST_WK MM_DOB YY4_DOB

Source: Author's construction based on Maryland PRAMS Phase 8 Questionnaire and Maryland Birth Certificates

These ten health indicators will be examined across selected subgroups: ethnicity (Hispanic or non-Hispanic), race (White, Black, Asian or Other Races), age (<35 years or ≥35 years), marital status (married or other including single, widowed or divorced), and education (<high school, high school, <college or ≥ college). In addition to maternal characteristics, the study will also stratify the health indicators by infant gestational age (<37 weeks or ≥ 37 weeks). Characteristics of the sample were captured using data from the birth certificate files (Table 11).

Table 11: Maternal & Infant Characteristics, Study Aim 2

Maternal & Infant Characteristics	Birth Certificate Variable
Maternal Race	MAT_RACE
Maternal Ethnicity	HISP_BC
Marital Status	MARRIED
Maternal Education	MAT_DEG
Infant Gestational Age	PRETERM_BC

Source: Author's construction based on Maryland Birth Certificates

Analysis Plan

There were six steps in the quantitative analysis plan to evaluate PRAMS system performance:

1) Survey Data Cleaning

Survey years 2016 and 2017 were selected because: (1) the PRAMS questionnaire was in its eighth phase and the same survey questions were used in 2016 and 2017, (2) Maryland did not meet the CDC response rate threshold of 55% for 2018 births and the data could not be published externally, and (3) the study needed to ensure sufficient sample size and statistical power. Once the PRAMS data and birth certificate data were received from the Maryland Department of Health, the data was cleaned using Stata statistical software. Survey data cleaning involved identifying and removing responses that were incomplete, outliers, or did not meet the study criteria.

2) Generation of New Variables

Most of the data fields from the PRAMS questionnaire and birth certificate files were analogous to one another and could be directly compared. There were a few health indicators that required the generation of new variables in order to parallel the PRAMS survey responses to information found on the birth certificate. These study variables included maternal nutrition, maternal age, prenatal care and maternal health insurance. For maternal nutrition, both data sources asked about maternal height and weight. The health indicator of interest was maternal body mass index (BMI), an indicator of malnutrition or obesity, and was calculated using a person's height and weight (BMI = kg/m^2). Data from the PRAMS questionnaire and birth certificate files were used to generate a new BMI variable for the purpose of the study. For maternal age, both data sources asked about the mother's date of birth. A new age variable was generated to reflect the age of the mother in years. For prenatal care, the study used the date of the first prenatal care visit and the

gestational estimate at delivery to determine the number of weeks of pregnancy during the first prenatal care visit. Data on maternal health insurance was captured in unique and dissimilar categories in the PRAMS survey and the birth certificate. The study used the health insurance categories provided by the birth certificate as the standard and sorted PRAMS' health insurance categories accordingly. Table 12 lists the maternal health insurance categories with the corresponding PRAMS and birth certificate variables used by the study.

Table 12: Maternal Health Insurance Categories

Category	Birth Certificate	PRAMS
1	Medicaid	Medicaid
2	Private Insurance	Insurance paid by job, parent, or Health Care Exchange
3	Self-Pay	No insurance
4	Champus/Tricare	Tricare or military insurance
5	Indian Health Service, Other Government Insurance, Other	Other

Source: Author's construction based on Maryland PRAMS Phase 8 Questionnaire and Maryland Birth Certificates

3) Demographics and Prevalence Estimates

Once the study data file was cleaned and the appropriate variables were generated, Stata was used to describe the demographics of the sample. Study demographics of interest included maternal age, race, ethnicity, marital status, education and preterm birth. Counts and percentages were calculated across demographic subgroups. Stata was also used to generate estimates for each of the ten study variables and included number of observations, means for continuous variables, proportions for dichotomous variables and 95% confidence intervals.

4) Sensitivity Analysis

Sensitivity is the proportion of mothers identified with the condition on birth certificates who are correctly identified by PRAMS self-report, represented by TP/(TP+FN) in the Table 13.

Table 13: 2×2 Table with PRAMS Self-Report and Birth Certificate

	Birth Certificate		
PRAMS	Risk Factor Present	Risk Factor Absent	Total
Self-Report Positive	True Positive (TP)	False Positive (FP)	TP + FP
Self-Report Negative	False Negative (FN)	True Negative (TN)	TN + FN
Total	TP + FN	TN + FP	

Source: Author's construction based on German et al (2001)

Stata was used to compute sensitivity for selected health indicators, as well as 95% confidence intervals. Sensitivity was categorized into three performance ratings: excellent (>90%), moderate (70-90%), or poor (<70%). Findings from the sensitivity analysis determined which health indicators perform well in recognizing mothers at greater risk of preterm births.

5) Positive Predictive Value (PPV) Analysis

Positive predictive value (PPV) is the proportion of mothers that truly have the condition that is correctly identified as having the condition by self-report, represented by TP/(TP+FP) in Table 13. Stata was used to compute PPV for selected health indicators, as well as 95% confidence intervals. Similar to sensitivity, PPV was categorized into three performance ratings: excellent (>90%), moderate (70-90%), or poor (<70%). Findings from the PPV analysis determined which health indicators perform well in identifying true positives among sampled mothers.

6) Interrater Agreement Analysis

Interrater agreement is the degree of agreement between PRAMS and the birth certificate to classify an individual into the same predefined category. The kappa statistic measure of agreement was used to measure interrater agreement. The kappa statistic is scaled to be 0 when the amount of agreement is what would be expected to be observed by chance and 1 when there is perfect agreement. For intermediate values, the study followed the following interpretations made by Landis and Koch[82]:

Table 14: Kappa-Statistic Interpretations

Kappa-Statistic Measure of Agreement	Interpretation
Below 0.0	Poor
0.00-0.20	Slight
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial
0.81-1.00	Almost Perfect

Source: Landis et al (1977)

The interrater agreement analysis determined how well PRAMS and birth certificate data files were in agreement with one another as two, independent data sources.

Table 15 indicates which study variables were included in the sensitivity, PPV and interrater agreement analyses. Dichotomous indicators were used for the sensitivity and PPV analyses, excluding continuous variables (maternal age, maternal nutrition and prenatal care) and nominal variables (maternal health insurance). All health indicators were included in the interrater agreement analysis.

Table 15: Study Variables for Sensitivity, PPV and Interrater Agreement Analyses

Health Indicator	Sensitivity	PPV	Interrater Agreement
1. Maternal Age			X
2. Maternal Nutrition – Mother's BMI			X
3. Maternal Health – Pre-pregnancy Hypertension	X	X	X
4. Maternal Health – Gestational Diabetes	X	X	X
5. Maternal Health Insurance			X
6. Reproductive History – Previous Live Births	X	X	X
7. Reproductive History – Previous Cesarean Delivery	X	X	X
8. Cigarette Smoking – Pre-pregnancy	X	X	X
9. Cigarette Smoking – Last 3 months of pregnancy	X	X	X
10. Prenatal Care			X

Source: Author's construction

Chapter 7: Results & Discussion– Study Aim 2

Results

Maternal Demographics

For the purpose of this study, the total number of observations included in the study analysis was 2,227 with a weighted response reflecting 130,056 participants. For birth year 2016, 1,167 mothers were included in the sample, reflecting a total of 65,852 Maryland mothers[79]. For birth year 2017, 1,060 mothers were included in the sample, reflecting a total of 64,204 Maryland mothers[78]. Maternal demographics were observed using information from the birth certificate. Weighted responses included 56,064 births to non-Hispanic Whites, 35,974 births to non-Hispanic Blacks, 23,418 births to Hispanics, 9,519 births to Asians, and 3,154 births to Other/Mixed.

The women included in the study sample had similar age distributions, with 95.2% of women being 25 years or older and of child-bearing age. The average age of respondents was 34 years, with the youngest respondent being 20 years old and the oldest respondent being 55 years old. Study participants were predominantly non-Hispanic White (43.1%), married (64.4%), completed a high school education or greater (87.5%), and had a term birth (76.6%). The study sample was reflective of the state of Maryland and the study data was assumed to be representative of the maternal population in Maryland. Table 16 lists the maternal and infant characteristics of PRAMS respondents included in the study sample. Study findings are shown by maternal age, race/ethnicity, marital status, education and infant gestational age.

Table 16: Maternal & Infant Characteristics

	Unweighted Count	Weighted Counts	Weighted Percentage Distribution
Maternal Age (in years) (n=2,227)			
< 20	0	0	0.0%
20-24	106	6,190	4.8%
25-34	1031	60,210	46.3%
≥ 35	1090	63,656	48.9%
Maternal Race/Ethnicity (n=2,198)			
Hispanic	401	23,418	18.0%
Non-Hispanic	1,793	104,711	80.5%
White	960	56,064	43.1%
Black	616	35,974	27.7%
Asian	163	9,519	7.3%
Other/Mixed	54	3,154	2.4%
Missing	33	1,927	1.5%
Marital Status (n=2,226)			
Married	1433	83,687	64.4%
Other	793	46,311	35.6%
Missing	1	58	0.00%
Maternal Education (n=2,210)			
≤ 8th Grade	108	6,307	4.9%
9-12 Grade	169	9,870	7.6%
High School	416	24,294	18.7%
Some College	408	23,827	18.3%
Associate Degree	142	8,293	6.4%
Bachelor's Degree	526	30,718	23.6%
Master's Degree	355	20,732	15.9%
Doctorate/Prof Degree	86	5,022	3.9%
Missing	17	993	0.7%
Infant Gestational Age (n=2,227)			
Preterm (<37 weeks)	522	30,485	23.4%
Term (≥37 weeks)	1,705	99,571	76.6%

Source: Author's calculation

Descriptive Statistics of Maternal Health Indicators

Table 17 presents the ten maternal health indicators included in the study. For each health indicator, descriptive statistics are shown from the self-reported PRAMS and birth certificate data. The descriptive statistics include means for continuous variables and proportions for dichotomous variables, as well as observation counts, 95% confidence intervals and differences between PRAMS and birth certificate data. The means for continuous variables from both data sources were similar, whereas the proportions were consistently higher on PRAMS than on birth certificates with the exception of maternal health insurance (proportion equal to birth certificate) and reproductive history – previous live births (proportion less than birth certificate). Maternal health insurance had the highest proportion on the PRAMS and the birth certificate, while cigarette smoking during the last 3 months of pregnancy had the lowest proportion on both data sources. For both PRAMS and birth certificate data, all estimates were within the 95% confidence intervals. Nine out of ten indicators had overlapping confidence intervals for PRAMS and birth certificates, signifying no statistical differences between the two data sources. The exception was previous cesarean deliver which did not have overlapping confidence intervals, suggesting a statistical difference between PRAMS and birth certificates for that indicator.

For most health indicators, the birth certificate had greater number of observations compared to PRAMS. Across all indicators, missing data ranged from 0-41% for PRAMS and 0-15% for birth certificates, indicating PRAMS had more data gaps. Previous cesarean delivery had the greatest number of missing data for PRAMS, resulting in the greatest difference in proportions. First prenatal care visit had the greatest number of missing data for birth certificates and the second greatest for PRAMS. Appendixes 10-19 provide the study's statistical data by health indicator.

Table 17: Prevalence of Maternal Health Indicators from PRAMS and Birth Certificate

	PRAMS			Birth Certificate			
Continuous Variables	**Obs**	**Means**	**95% CI**	**Obs**	**Means**	**95% CI**	**Difference in Means**
Maternal Age (years)	2,184	34.78	(34.54-35.01)	2,227	34.74	(34.51-34.98)	0.04
Maternal Nutrition – Mother's BMI	2,055	26.55	(26.27-26.83)	2,160	26.94	(26.66-27.22)	0.39
First Prenatal Care Visit (weeks)	1,850	12.33	(12.03-12.64)	1,887	12.32	(12.02-12.61)	0.01
Categorial Variables	**Obs**	**Proportions**	**95% CI**	**Obs**	**Proportions**	**95% CI**	**Difference in Proportions**
Maternal Health – Gestational Hypertension	2,193	0.15	(0.13-0.17)	2,226	0.12	(0.11-0.14)	0.03
Maternal Health – Gestational Diabetes	2,191	0.10	(0.09-0.12)	2,226	0.08	(0.07-0.09)	0.02
Maternal Health Insurance	2,083	0.96	(0.95-0.97)	2,218	0.96	(0.96-0.97)	0.0
Reproductive History – Previous Live Births	2,208	0.59	(0.57-0.61)	2,227	0.61	(0.59-0.63)	0.02
Reproductive History – Previous Cesarean Delivery	1,313	0.30	(0.27-0.32)	2,227	0.13	(0.12-0.15)	0.17
Cigarette Smoking –Pre-pregnancy	2,227	0.12	(0.10-0.13)	2,218	0.09	(0.08-0.10)	0.03
Cigarette Smoking –Last 3 months of pregnancy	2,227	0.06	(0.05-0.07)	2,219	0.04	(0.03-0.05)	0.02

Source: Author's calculation

Sensitivity

This study defined sensitivity as the proportion of mothers identified with the condition on birth certificates who were correctly identified by PRAMS self-report (true positives / true positives plus false negatives). Six dichotomous health indicators were used for the sensitivity analysis conducted in Stata. Table 18 presents the sensitivity and 95% confidence intervals by health indicator. It also presents the performance rating (excellent >90%, moderate 70-90%, and poor <70%) for all six indicators. Sensitivity ranged from 66.67% for gestational hypertension to

98.61% for previous cesarean delivery. Out of the six health indicators included in the sensitivity analysis, three indicators were excellent, two were moderate, and one was poor.

Table 18: Sensitivity of Maternal Health Indicators

Health Indicator	Sensitivity (%)	95% CI (%)	Performance Rating
Reproductive History – Previous Cesarean Delivery	98.61	(96.47-99.62)	Excellent
Reproductive History – Previous Live Births	96.43	(96.43-97.35)	Excellent
Cigarette Smoking – Last 3 months of pregnancy	92.63	(85.41-96.99)	Excellent
Cigarette Smoking – Pre-pregnancy	87.05	(81.47-91.44)	Moderate
Maternal Health – Gestational Diabetes	86.74	(80.92-91.32)	Moderate
Maternal Health – Gestational Hypertension	66.67	(60.70-72.26)	Poor

Source: Author's calculation

Positive Predictive Value (PPV)

This study defined positive predictive value as the proportion of mothers that truly had the condition that were correctly identified as having the condition by self-report (true positives / true positives plus false positives). Similar to the sensitivity analysis, the same six health indicators were used for the positive predictive value analysis. Table 19 presents the positive predictive values, 95% confidence intervals and performance ratings by health indicator (excellent >90%, moderate 70-90%, and poor <70%). PPV ranged from 54.88% for gestational hypertension to 98.70% for previous live births. Out of the six health indicators included in the PPV analysis, one indicator was excellent, one was moderate, and four were poor.

Table 19: Positive Predictive Value (PPV) of Maternal Health Indicators

Health Indicator	Positive Predictive Value (%)	95% CI (%)	Performance Rating
Reproductive History – Previous Live Births	98.70	(97.94-99.19)	Excellent
Reproductive History – Previous Cesarean Delivery	72.38	(68.66-75.81)	Moderate
Maternal Health – Gestational Diabetes	69.16	(63.89-73.98)	Poor
Cigarette Smoking – Last 3 months of pregnancy	68.75	(61.69-75.04)	Poor
Cigarette Smoking – Pre-pregnancy	64.12	(59.29-68.69)	Poor
Maternal Health – Gestational Hypertension	54.88	(50.49-59.19)	Poor

Source: Author's calculation

Table 20 presents a summary table of the performance ratings for sensitivity and PPV, and categorizes the health indicators by materal experiences, health behaviors and health conditions. Measures of sensitivity and PPV varied from poor to excellent, with PPV having the largest number of poor ratings. Sensitivity and PPV had identical ratings for two health indicators: Gestational Hypertension (poor) and Previous Live Births (excellent). The largest disagreement between sensitivity and PPV was for cigarette smoking in the last 3 months of pregnancy. This indicator also had the lowest proportion among the sampled population.

Table 20: Summary of Sensitivity and Positive Predictive Value Performance Ratings

Health Indicator	Sensitivity Rating	Positive Predictive Value Rating
Maternal Experiences		
Reproductive History – Previous Live Births	Excellent	Excellent
Reproductive History – Previous Cesarean Delivery	Excellent	Moderate

Health Indicator	Sensitivity Rating	Positive Predictive Value Rating
Health Behaviors		
Cigarette Smoking – Pre-pregnancy	Moderate	Poor
Cigarette Smoking – Last 3 months of pregnancy	Excellent	Poor
Health Conditions		
Maternal Health – Gestational Hypertension	Poor	Poor
Maternal Health – Gestational Diabetes	Moderate	Poor

Source: Author's calculation

Interrater Agreement

All ten health indicators were used for the interrater agreement analysis. Table 21 presents the kappa statistic and the Landis and Koch interpretation of all health indicators (almost perfect 0.81-1.00, substantial 0.61-0.80, moderate 0.41-0.60, fair 0.21-0.40, slight 0.00-0.20, and poor <0.00). The kappa statistics ranged from 0.3704 for maternal BMI to 0.9946 for first prenatal care visit. Out of the ten health indicators included in the interrater agreement analysis, three indicators were almost perfect, four were substantial, two were moderate, and one was fair.

Table 21: Interrater Agreement of Maternal Health Indicators

Health Indicator	Kappa Statistics	Agreement	Prob>Z	Interpretation
First Prenatal Care Visit	0.9946	99.46%	0.0000	Almost Perfect
Maternal Age	0.9675	96.75%	0.0000	Almost Perfect
Reproductive History – Previous Live Births	0.9386	97.06%	0.0000	Almost Perfect
Reproductive History – Previous Cesarean Delivery	0.7791	91.47%	0.0000	Substantial
Cigarette Smoking – Last 3 months of pregnancy	0.7783	97.88%	0.0000	Substantial
Maternal Health – Gestational Diabetes	0.7463	95.71%	0.0000	Substantial
Cigarette Smoking – Pre-pregnancy	0.7095	94.66%	0.0000	Substantial

Health Indicator	Kappa Statistics	Agreement	Prob>Z	Interpretation
Maternal Health – Gestational Hypertension	0.5398	89.14%	0.0000	Moderate
Maternal Health Insurance	0.5380	73.20%	0.0000	Moderate
Maternal Nutrition – Mother's BMI	0.3704	40.40%	0.0000	Fair

Source: Author's calculation

Sensitivity, PPV and Interrater Agreement by Selected Maternal Demographic Characteristics

When stratified by selected maternal and infant demographic characteristics, the differences in sensitivity, PPV and interrater agreement varied among the ten health indicators examined, as shown in Tables 22-25. Light gray shading represents the lowest measurements across characteristics and health indicators. Sensitivity ranged from 37.04% for women with less than a high school education reporting on gestational hypertension to 100.00% for several groups including Asian women reporting on previous cesarean delivery and Other/Mixed women reporting on gestational diabetes and first prenatal care visit. When stratified by maternal race, sensitivity was lower for Hispanic women, non-Hispanic Black women, and women of other/mixed races across most health indicators. Sensitivity was also observed to be lower for women aged 35 or younger, women with 11 years of education or less, and women with term infants. PPV ranged from 27.78% for women with less than a high school education reporting on gestational hypertension to 100.00% for Other/Mixed women reporting on pre-pregnancy smoking and third trimester smoking. When stratified by maternal age and marital status, PPV was generally lower for women under 35 years old and those who were single, divorced or widowed. For maternal race, PPV was observed to be lower among non-Hispanic Black women and women of other/mixed races. Kappa statistic ranged from 0.1157 for women with less than a high school education reporting on maternal health insurance to 1.000 for Other/Mixed women reporting on third trimester smoking. The lowest kappa statistics were observed among Hispanic women,

women less than 35 years old and unmarried women. When stratified by maternal education, kappa statistic was lowest for women with less than a college degree with the exception of cigarette smoking, which was lowest for women with a college degree or higher.

Table 22: Sensitivity, PPV and Interrater Agreement for Gestational Hypertension and Gestational Diabetes, by Selected Maternal & Infant Characteristics

	Gestational Hypertension				Gestational Diabetes			
Characteristics	Sensitivity (%)	PPV (%)	Agreement (%)	Kappa Statistic	Sensitivity (%)	PPV (%)	Agreement (%)	Kappa Statistic
Maternal Race/Ethnicity								
Hispanic	57.78	53.06	89.81	0.4958	86.96	72.73	94.89	0.7632
Non-Hispanic	68.44	55.40	89.01	0.5492	86.67	68.42	95.94	0.7428
White	69.03	56.52	90.06	0.5650	87.27	73.85	97.48	0.7867
Black	68.82	55.17	86.57	0.5324	83.33	61.54	94.55	0.6786
Asian	66.67	53.33	93.08	0.5553	88.89	70.59	91.82	0.7371
Other/Mixed	57.14	44.44	85.19	0.4146	100.00	71.43	96.23	0.8127
Maternal Age								
< 35 years	65.75	52.75	87.77	0.5146	90.12	66.97	96.06	0.7474
≥ 35 years	67.74	57.53	90.56	0.5687	84.00	71.19	95.34	0.7449
Marital Status								
Married	65.06	58.06	90.38	0.5589	85.71	70.59	95.54	0.7497
Other	69.23	50.70	86.87	0.5096	89.09	66.22	96.00	0.7384
Maternal Education								
≤ 11 years	37.04	27.78	83.96	0.2286	79.31	62.16	92.59	0.6555
12 years	72.00	57.14	89.98	0.5799	89.74	74.47	96.07	0.7922
13-15 years	70.89	58.33	88.35	0.5713	84.38	55.10	94.99	0.6409
≥ 16 years	69.03	59.54	90.80	0.5870	88.89	76.60	96.76	0.8051
Infant Gestational Age								
Preterm (<37 weeks)	77.78	64.81	83.17	0.5904	86.79	63.89	93.57	0.7003
Term (≥37 weeks)	55.56	45.18	90.99	0.4494	86.72	71.61	96.36	0.7648

Source: Author's calculation

Table 23: Sensitivity, PPV and Interrater Agreement for Previous Live Births and Previous Cesarean Delivery, by Selected Maternal & Infant Characteristics

	Previous Live Births				Previous Cesarean Delivery			
Characteristics	Sensitivity (%)	PPV (%)	Agreement (%)	Kappa Statistic	Sensitivity (%)	PPV (%)	Agreement (%)	Kappa Statistic
Maternal Race/Ethnicity								
Hispanic	95.71	99.32	96.38	0.9105	97.01	75.58	92.23	0.7984
Non-Hispanic	96.62	98.53	97.21	0.9429	99.09	71.48	91.22	0.7733
White	96.51	98.50	97.18	0.9427	99.07	71.81	91.95	0.7814
Black	96.56	99.18	97.40	0.9456	98.84	69.67	89.59	0.7475
Asian	97.62	96.47	96.88	0.9373	100.00	80.77	94.05	0.8529
Other/Mixed	96.43	96.43	96.23	0.9243	100.00	62.50	89.29	0.7042
Maternal Age								
< 35 years	96.14	98.40	96.92	0.9374	98.46	70.33	91.46	0.7665
≥ 35 years	97.14	99.47	97.50	0.9370	98.73	74.16	91.48	0.7896
Marital Status								
Married	96.78	98.82	97.33	0.9441	98.95	74.02	92.01	0.7943
Other	95.78	98.48	96.56	0.9286	97.94	69.34	90.48	0.7507
Maternal Education								
≤ 11 years	95.77	99.03	95.96	0.8859	95.56	69.35	89.86	0.7376
12 years	96.72	98.88	97.09	0.9353	100.00	73.02	93.70	0.8058
13-15 years	97.31	98.78	97.61	0.9500	98.68	69.44	89.70	0.7467
≥ 16 years	96.09	98.59	97.19	0.9437	99.14	75.66	92.32	0.8069
Infant Gestational Age								
Preterm (<37 weeks)	92.00	99.28	94.98	0.8984	96.10	77.89	91.37	0.7990
Term (≥37 weeks)	97.70	98.55	97.69	0.9513	99.52	70.61	91.50	0.7720

Source: Author's calculation

Table 24: Sensitivity, PPV and Interrater Agreement for Cigarette Smoking (Pre-pregnancy & Last 3 Months of Pregnancy), by Selected Maternal & Infant Characteristics

	Cigarette Smoking – Pre-pregnancy				Cigarette Smoking – Last 3 Months of Pregnancy			
Characteristics	Sensitivity (%)	PPV (%)	Agreement (%)	Kappa Statistic	Sensitivity (%)	PPV (%)	Agreement (%)	Kappa Statistic
Maternal Race/Ethnicity								
Hispanic	77.78	30.43	95.77	0.4199	100.00	66.67	99.76	0.7989
Non-Hispanic	87.91	67.23	94.43	0.7310	93.48	68.80	97.49	0.7796
White	93.28	68.52	93.85	0.7550	93.94	74.70	97.39	0.8183
Black	77.97	65.71	93.99	0.6799	91.67	57.89	97.07	0.6951
Asian	N/A	N/A	98.16	0.0000	N/A	N/A	98.77	0.0000
Other/Mixed	75.00	100.00	98.15	0.8475	100.00	100.00	100.00	1.0000
Maternal Age								
< 35 years	86.46	64.34	94.81	0.7097	94.87	66.07	98.15	0.7696
≥ 35 years	87.63	63.91	94.50	0.7092	91.07	70.83	97.61	0.7844
Marital Status								
Married	84.21	48.48	95.81	0.5949	95.65	56.41	98.74	0.7037
Other	88.24	74.07	92.69	0.7608	91.67	75.00	96.46	0.8055
Maternal Education								
≤ 11 years	83.72	75.00	93.14	0.7253	92.59	78.13	96.70	0.8291
12 years	89.86	72.09	92.55	0.7549	94.59	71.43	96.15	0.7930
13-15 years	88.33	65.43	93.64	0.7162	88.46	69.70	97.63	0.7673
≥ 16 years	84.21	36.36	96.79	0.4941	100.00	33.33	99.17	0.4969
Infant Gestational Age								
Preterm (<37 weeks)	95.74	62.50	94.44	0.7265	95.83	57.50	96.55	0.7016
Term (≥37 weeks)	84.25	64.74	94.72	0.7034	91.55	73.86	98.29	0.8088

Source: Author's calculation

Table 25: Sensitivity, PPV and Interrater Agreement for Maternal Age, BMI, First Prenatal Care Visit, and Health Insurance, by Selected Maternal & Infant Characteristics

	Maternal Age		Maternal Nutrition – Mother's BMI		First Prenatal Care Visit		Maternal Health Insurance	
Characteristics	Agreement (%)	Kappa Statistic	Agreement (%)	Kappa Statistic	Agreement (%)	Kappa Statistic	Agreement (%)	Kappa Statistic
Maternal Race/Ethnicity								
Hispanic	94.92	0.9490	29.59	0.2544	99.15	0.9914	43.68	0.2308
Non-Hispanic	97.17	0.9717	42.24	0.3900	99.53	0.9953	79.55	0.6058
White	98.32	0.9832	46.71	0.4320	99.51	0.9951	85.27	0.6370
Black	96.01	0.9601	35.01	0.3214	99.79	0.9979	71.13	0.5041
Asian	96.23	0.9620	41.03	0.3628	99.27	0.9926	82.43	0.6050
Other/Mixed	92.16	0.9201	40.82	0.3684	100.00	1.0000	62.75	0.3948
Maternal Age								
< 35 years	96.49	0.9649	39.73	0.3614	99.22	0.9922	72.79	0.5236
≥ 35 years	97.10	0.9701	41.10	0.3791	99.68	0.9968	73.64	0.5517
Marital Status								
Married	97.44	0.9744	44.64	0.4125	99.51	0.9951	80.62	0.5792
Other	95.48	0.9548	32.21	0.2884	99.36	0.9936	59.14	0.3209
Maternal Education								
≤ 11 years	95.93	0.9591	19.41	0.1518	98.63	0.9862	40.35	0.1157
12 years	95.56	0.9554	30.48	0.2711	99.69	0.9969	60.79	0.2975
13-15 years	96.68	0.9667	39.81	0.3679	99.11	0.9910	70.55	0.5014
≥ 16 years	97.69	0.9768	48.72	0.4525	99.76	0.9976	88.18	0.5984
Infant Gestational Age								
Preterm (<37 weeks)	97.08	0.9708	41.18	0.3809	99.25	0.9925	70.06	0.4904
Term (≥37 weeks)	96.65	0.9664	40.16	0.3668	99.52	0.9951	74.18	0.5530

Source: Author's calculation

Discussion

This study adds to the existing research of self-reported, population-based surveillance systems by revealing the validity and reliability of selected indicators on the Pregnancy Risk Assessment Monitoring System. When compared to birth certificates, PRAMS had relatively high sensitivity, low PPV and high overall agreement on selected proximate determinates of preterm birth. These findings validated inferences from study aim 1 by confirming sensitivity as a strength of the PRAMS surveillance system and positive predictive value as a limitation.

Overall, PRAMS reported higher proportions of health-related indicators compared to birth certificates, indicating PRAMS' effectiveness in meeting its surveillance objectives to report state-level prevalence data on health behaviors related to pregnancy risk. The study findings were consistent with published reports that have shown women are able to recall health events related to pregnancy with relative accuracy [64] [83] [84]. Previous studies assessing the quality of PRAMS self-reported data have found that women's recall of events during the prenatal and early postnatal period was closely matched to provider-reported or administrative records[83] [84].

Birth Certificates

For the purpose of this study, the U.S. Standard Certificate of Live Birth was identified as the reference standard (true positives and true negatives) because it was a common and widely used data source for maternal and infant health indicators at the state and national levels. Since PRAMS data were self-reported, it was important to examine its reliability and validity against an established population-based data collection system. Birth certificates have been previously used by other studies as a standard for assessing PRAMS self-reported data[64] [83]. Literature on birth certificates observed that many data elements were accurate when compared to medical records as the gold standard and reported that sensitivity may vary by subgroup of mothers and how rare the condition was in the population [65] [85] [86].

Sensitivity

Using the study's performance rating system for sensitivity, half of the maternal health indicators that were proximate determinates of preterm births fell in the excellent category. These indicators included previous live births, previous cesarean delivery and third trimester cigarette smoking. Previous cesarean delivery had the greatest sensitivity (98.61%). Multiple indicators with excellent

sensitivity ratings signified that PRAMS had the ability to identify mothers with selected behaviors and experiences. Furthermore, it implied that for indicators with high sensitivity, PRAMS had few false negative results and fewer health-related events were missed by the surveillance system. The study findings confirmed inferences made in study aim 1 that identified sensitivity as a strength of the PRAMS system. Findings were also comparable to other previously published reports that noted moderate to high sensitivity of PRAMS indicators[64 65].

Gestational diabetes and pre-pregnancy cigarette smoking had moderate sensitivity performance ratings. Gestational hypertension had a poor performance rating and the lowest sensitivity (66.67%). The moderate and poor performance ratings suggest that PRAMS was less likely to identify mothers with these selected health indicators. For gestational diabetes and gestational hypertension, it is possible that respondents were less familiar with the medical terminology used in the questionnaire (i.e. gestational, diabetes, hypertension, pre-eclampsia and eclampsia). Mothers may be diagnosed with such conditions but were not able to correctly identify themselves on the questionnaire due to their level of medical competency and health literacy. Additionally, mothers may have difficulty reporting gestational diabetes and gestational hypertension if they were not told by their healthcare provider that they had those conditions, or the provider used other terminology to explain their condition. The PRAMS questionnaire aimed to account for this barrier by including simple definitions, reducing opportunities of misunderstanding. For example, on the questionnaire, gestational diabetes was defined as diabetes that "started during this pregnancy" and gestational hypertension was defined as high blood pressure that "started during this pregnancy."

For pre-pregnancy smoking behavior, a moderate performance rating may be attributed to the stigmatization of smoking, especially surrounding pregnancy. Mothers are more likely to under-

report smoking behavior if they are aware of the pregnancy outcomes associated with smoking. This was consistent with other studies that found under-reporting of active smoking because the mother chose not to reveal her true smoking behavior[87].

Positive Predictive Value (PPV)

Positive predictive value performed consistently lower than sensitivity on all health indicators. Using the study's performance rating system for PPV, the majority of the maternal health indicators fell in the poor category. These indicators included gestational hypertension, gestational diabetes, pre-pregnancy cigarette smoking and third trimester cigarette smoking. Gestational hypertension had the lowest PPV (54.88%). For health indicators with poor PPV performance ratings, it was possible that PRAMS had a greater number of false positives when compared to birth certificates. These false positives can be attributed to low prevalence of health-related events in the population of interest. Study results confirmed that every indicator with a poor PPV rating also had a low prevalence, between 6% and 15%. Consistent with screening evaluation research, it is not uncommon for a surveillance system to have high sensitivity and a low positive predictive value if the prevalence of the health-related event in question is low in the population[88]. Findings supported study aim 1 that suggested PPV was a limitation of the PRAMS surveillance system. In addition, it confirmed findings from Dietz (2014) that PPV had the largest number of poor ratings and contradicted Ahluwalia (2013) that measured moderate to high PVP on three selected PRAMS indicators [64] [65].

Another explanation for PRAMS' low PPV performance ratings is over-reporting on the questionnaire and under-reporting at time of delivery. For cigarette smoking, mothers who smoke may be more comfortable sharing their true status on the anonymous, self-reported questionnaire

and more likely to under-report their smoking status to a doctor, nurse or mid-wife prior to hospital discharge. This was consistent with a study that found systematic differences in reporting of prenatal smoking in PRAMS and birth certificates. To account for prenatal smoking difference, Allen (2008) suggested that women who were older and more educated were more likely to admit smoking in the confidential, self-administered questionnaire than to a provider[83]. Another scenario is that mothers may over-report medical conditions such as gestational hypertension because they have misclassified themselves. Gestational hypertension is a diagnosis that requires high blood pressure readings at two separate visits. Women who screened for high blood pressure during the first visit and normal blood pressure during the second visit may mistakenly misclassify themselves as having gestational hypertension. A similar situation occurs with gestational diabetes which requires a positive result on two different glucose tests. This discrepancy will lead to increased false positives on the PRAMS questionnaire when compared to the birth certificate as the reference standard.

Although a high PPV is desirable to minimize false positives, a lower PPV may be acceptable under certain circumstances for surveillance systems. For example, for gestational hypertension and diabetes, false positives will lead to increased follow-up and prenatal care visits which may not be opposed if it does not increase burden on the mother and the healthcare provider. Additionally, false positives might be acceptable if no harm is done to the mother in protecting her against the condition even if that condition is not present. For example, whether the mother identifies as a smoker or a non-smoker, she will benefit from discussing smoking behavior with her healthcare provider. Similarly, regardless of her prevalence of smoking (<1 cigarette per day or 41+ cigarettes per day), mothers will benefit from smoking cessation education and adopting advice to discontinue smoking and improve their health.

Interrater Agreement

This study showed a high degree of overall agreement among the self-reported PRAMS and birth certificate. In the study's interpretation of the kappa statistics, the majority of the maternal health indicators fell into the top two categories of interrater agreement: almost perfect and substantial. For the almost perfect level of agreement, these indicators included maternal age, first prenatal care visit and previous live birth. First prenatal care visit had the highest kappa statistics, indicating that the agreement between PRAMS and the birth certificate was 99.46% of the way between random agreement (0.00) and perfect agreement (1.00). For the substantial level of agreement, these indicators included gestational diabetes, previous cesarean delivery, pre-pregnancy cigarette smoking and third trimester cigarette smoking. For most study indicators, there was agreement or consensus between the self-reported PRAMS questionnaire and the birth certificates. This was similar to findings from Ahluwalia (2013) that reported high agreement among self-reported WIC participation during pregnancy, Medicaid payment for delivery and breastfeeding indicators on PRAMS and birth certificates, suggesting that PRAMS self-reported data on these indicators were reliable and valid[64].

Maternal BMI had the lowest kappa statistics (0.3704). The study data showed that PRAMS and the birth certificate agreed on 40.40% of the respondents and 37.04% of the way between random agreement and perfect agreement. Likely reasons for the low agreement are human error, measurement error, differences in weight at time of data collection, and recall bias. BMI is calculated using two measurements: height and weight. Both measurements are subjected to human errors such as misreading the measuring instruments or documentation inaccuracies. Measurement error can be caused by the utilization of different measuring instruments, mis-calibrated instruments and differences in clothing and shoes worn during time of measurement. A

women's weight fluctuates between pre-pregnancy and delivery, leading to possible minor discrepancies between the two data sources and recall bias. Equally, it was important to mention that there were no slight (0.00-0.20) ratings or poor (<0.00) ratings for interrater agreement, signifying credible overall agreement between PRAMS and birth certificates.

Performance Across System Attributes

It was worth noting that each of the ten maternal health indicators included in the study performed differently in the sensitivity, PPV and interrater agreement analyses. This was consistent with a previous study that observed that measures of PRAMS sensitivity and PPV varied, with PPV having the largest number of poor performance ratings[65]. Previous live births performed the best, receiving the highest ratings in all three attributes. This study finding was in line with earlier research studies that reported previous live births to have overall excellent ratings[89]. Out of the remaining nine indicators, four indicators were top performers in at least one of the three surveillance system attributes. These top performers included maternal age, first prenatal care visit, previous cesarean delivery and third trimester cigarette smoking. Gestational diabetes, gestational hypertension, maternal BMI, maternal health insurance and pre-pregnancy cigarette smoking did not receive top ratings for any attribute. The variability in attribute performances emphasizes the need to evaluate the PRAMS survey by individual indicators in order to assess the validity and reliability of the self-reported data.

The maternal health indicators can be arranged into three categories: maternal experiences, health behaviors and health conditions. Indicators that asked about maternal experiences (i.e. previous live births, previous cesarean delivery and first prenatal care visit) were top performers that ranked high in at least one of the three surveillance system attributes. They had excellent sensitivity,

moderate to excellent PPV and substantial to almost perfect interrater agreement. This evidenced that mothers were able to recall past events rather accurately and that recall bias was not an issue for indicators relating to maternal experiences. Health behavior indicators (i.e. cigarette smoking) did not perform as well as maternal experience indicators. They had moderate to excellent sensitivity, poor PPV and substantial interrater agreement. This suggested that mothers were more likely to report behaviors on the anonymous PRAMS survey than to a healthcare provider due to self-reporting bias and that recall bias may play a role in reporting health behaviors. Health conditions (i.e. gestational hypertension and gestational diabetes) performed worse than maternal experience indicators and health behavior indicators. They had moderate to poor sensitivity, poor PPV and moderate to substantial interrater agreement. These findings imply mothers are more likely to truthfully report experiences and behaviors on the PRAMS questionnaire rather than medical conditions.

Performance by Maternal & Infant Characteristics

The study stratified findings by maternal and infant characteristics to further explore performance among sub-groups. When stratified by maternal race, women of other/mixed races were more likely to have poorer performances on sensitivity, PPV and interrater agreement when compared to other groups (White, Black and Asian). Hispanic women were more likely to have discrepancies between PRAMS and birth certificates, signified by lower kappa statistics. The pattern of lower agreement for Hispanic women may be explained by lower English proficiency if Hispanic women responded to an English version of the PRAMS survey, as well as distrust of the government. Unmarried women and women under 35 years performed significantly lower on sensitivity, PPV and interrater agreement when compared to married women and women 35 years or older, respectively. For infant gestational age, women with preterm births were more likely to have

poorer attribute performances compared with women with term births. This finding on preterm birth was similar to studies that reported recall among women who experienced pregnancy complications or whose infants experienced health problems may differ from those women who did not experience such health problems[14 90]. This may be attributed to their ability to accurately remember past events prior to having a preterm birth, particularly for behaviors and experiences that occurred early in the pregnancy.

When stratified for maternal education, women with less than a high school degree were more likely to have lower sensitivity, PPV and interrater agreement compared to women that have a high school degree or greater. Literature on the associations between years of education and health literacy reported that less years of education was associated with lower health literacy[91]. It was possible that low health literacy affected how respondents identified their health status, as well as their ability to understand and interpret health questions on the PRAMS questionnaire, leading to lower validity and reliability. It was interesting to note an exception for cigarette smoking, which had lower interrater agreement for women with a college degree or greater. This finding was consistent with Allen (2008) that found women with greater number of years of education were significantly more likely to report smoking on the PRAMS questionnaire and not on birth certificates[83]. This may indicate that these women are more likely to admit smoking behavior in a confidential questionnaire than to a healthcare provider, leading to reporting bias and underestimated prevalence data.

Limitations

The study is subject to several limitations. First, there was no perfect gold standard for PRAMS comparison. The study used birth certificate data as the reference standard; however, this data was

subjected to human errors and biases. It also had gaps in information as very few of the maternal health indicators had data for the total sample (n=2,227). Medical records and discharge data were other potential reference standards that could have been used for analysis and may be better for surveillance of medical conditions. However, the possibility remained that maternal conditions and behaviors may not have been recorded in the medical records and discharge data, leading to erroneous estimates.

A second limitation was that the study only included Maryland PRAMS and birth certificate data. Maryland's PRAMS survey was unique to the state, and the way birth certificate data was collected may vary from other states. Consequently, the study results were generalizable to the Maryland population. The varying demographics across states also limited the generalizability of the study findings to other states. However, study findings may apply to states with similar demographics to Maryland and to states with preterm births rates greater than the national average.

A third limitation was that the maternal health indicators selected for this study did not reflect the full range of proximate determinates of preterm birth. The study included indicators that were found in both the PRAMS questionnaire and the birth certificate. There are additional indicators that are determinants of preterm birth that were not included in the study because they were not included in both the PRAMS questionnaire and the birth certificate. Examples of these indicators included preconception care and readiness, alcohol use, stress, abuse and use of assisted reproductive technologies.

A final limitation was information gaps in the data sources. Most maternal health indicators had greater observations for the birth certificate than PRAMS. This signified that PRAMS was more

likely to have missing information because mothers omitted responses and failed to complete the survey in its entirety.

Recommendations

The study includes two recommendations for CDC PRAMS and participating PRAMS sites. Based on study findings, it is recommended that stakeholders use the PRAMS surveillance system to capture information on indicators relating to past and recent maternal experiences and health behaviors only and use birth certificates to capture information on health conditions. PRAMS proved to be more reliable for experience and behavior indicators and less reliable for health conditions. PRAMS is an effective tool for identifying selected behaviors and experiences among mothers and should continue to be used for national surveillance of pregnancy risk. However, it is worth noting that PRAMS is subject to common shortcomings of self-reported questionnaires as respondents may not reveal private details (social desirability bias), forget pertinent details (recall bias), or be influenced by their feelings at the time they are completing the questionnaire.

This study proved that it was essential to assess each PRAMS indicator individually to determine validity. It is recommended that the PRAMS program adopt a validation procedure to confirm the conditions self-reported on the questionnaire. Selected PRAMS indicators involving medically diagnosed conditions (i.e. diabetes, hypertension, asthma, anemia, depression, anxiety, etc.) can be validated by trusted, external data sources such as medical records or screening/diagnosis tests if available. For example, self-reported diabetes can be confirmed by a glucose test, hypertension by a high blood pressure screening, asthma by a spirometry test, anemia by a complete blood count test, and depression and anxiety by a mental health provider. Validating these PRAMS indicators

will require additional resources and provide data users with increased confidence that each indicator was carefully assessed for validity and reliability.

Chapter 8: Implications

The study findings present implications for PRAMS in practice, research and policy, as well as recommendations for future research.

Implications for Practice

For practice, study findings contributed to validating PRAMS as a national public health surveillance system for pregnancy risk. It confirmed the ability of the surveillance system to effectively track pregnancy-related health indicators over time, monitor maternal health behaviors and practices, assess program development needs, and evaluate programs serving women along the pregnancy continuum. For example, many states confirmed using PRAMS data to set State Health Improvement Plans (SHIP) priorities and track advancements toward those priorities. One state confirmed using PRAMS data to determine funding and to prioritize the allocation of resources for different counties; and another state used PRAMS data to train nurses and WIC personnel on breastfeeding initiatives.

For PRAMS, the study findings generated recommendations to improve PRAMS' performance on surveillance system attributes. These suggested next steps to improve performance can potentially position PRAMS as the prominent surveillance system in the MCH community, as well as a model for other national surveillance systems. Moreover, study findings encouraged further consideration of PRAMS strengths and limitations when using PRAMS data for practice (i.e. the availability of actionable data for emerging and current MCH issues). Finally, the study emphasized the need for periodic evaluations of public health surveillance systems. These evaluations measure how well systems operate to meet their purpose and objectives.

Implications for Research

For research, study findings provided a better understanding of the strengths and limitations of maternal health indicators on PRAMS, as well as self-reported health indicators in general. The study findings revealed that thoughtful considerations regarding system attributes were necessary for the appropriate use of PRAMS data by researchers and to inform research efforts of those relying on self-reported information. When using self-reported indicators, researchers should carefully consider the importance of sensitivity and positive predictive value metrics for validity and interrater agreement metrics for reliability. Such considerations provided direction on the accuracy of self-reported information. Researchers should also consider the remaining attributes of the surveillance system used for data collection. This information will inform researchers of how successful the system was at meeting its objectives. Lastly, the study findings have contributed to overall research efforts evaluating public health surveillance systems. When using public health surveillance systems, appropriate questions researchers should consider include:

- What are the purpose and objectives of the surveillance system?
- What system attributes are of the highest priority for the surveillance system?
- How valid and reliable are self-reported indicators captured by the system?

Implications for Policy

For policy, the study findings confirmed the PRAMS surveillance system as an important source for maternal and infant health data at the state- and national-level. Some states confirmed using PRAMS data to develop reports for legislative stakeholders to support policy decisions. One state produced a legislative report on the efficacy of baby boxes and recommendations regarding the utilization of baby boxes across the state at the hospital level. Another state was developing a

maternal mental health report to be presented in an upcoming legislative session. Similar to researchers, identifying PRAMS strengths and limitations will help policy makers use PRAMS data appropriately for policy decision making. Data-driven policymakers are interested in the collection and analysis of data to spotlight problem areas and potential solutions. They are also interested in developing quantifiable measures to assess policies targeting the MCH community, as well as identifying and expanding best practices. In order to accomplish these objectives, policymakers rely on operational systems to gather, analyze and disseminate actionable data. Study findings verified that the PRAMS system produced robust data that was relatively truthful and representative for influential MCH health indicators, giving policymakers confidence in using PRAMS data to inform governing policies.

Generalizability of Results

Results from study aim 1 are extensively generalizable to all participating PRAMS sites, including sites that did not participate in the research study. The findings may also be generalized to other public health surveillance systems that have similar structure as the PRAMS system (i.e. national surveillance system sponsored by a federal agency, dual-modes, self-reports, etc.). Differences in purpose, objectives and attribute priorities should be considered when adopting study finding to other surveillance systems.

Results from study aim 2 are not widely generalizable to all participating PRAMS sites because each site has a unique PRAMS survey and variations in how birth certificate data is collection. However, the study may provide implications for states similar to Maryland with diverse demographics and high preterm births rates.

Recommendations for Future Research

Future research studies may consider a compare and contrast investigation of PRAMS to another similar public health surveillance system using the nine system attributes described by CDC. Such an investigation will expand the findings of this study by revealing how PRAMS performs in relation to another national surveillance system, forming a basis of comparison. It can potentially lead to the benchmarking of national surveillance systems in the United States to identify strengths and weaknesses of each system. Comparable public health surveillance systems include the Behavioral Risk Factor Surveillance System (BRFSS), the Pregnancy Nutritional Surveillance System (PNSS), and the National Maternal and Infant Health Survey (NMIHS).

Future studies assessing the validity and reliability of additional PRAMS self-reported indicators will be valuable to PRAMS research, as well as other surveillance systems relying on self-reported information. This study assessed several PRAMS self-reported maternal and infant health indicators including maternal age, nutrition, prenatal care, gestational hypertension, gestational diabetes, health insurance, reproductive history and cigarette smoking. Prior research studies have assessed other indicators such as preceding preterm births, low birth weights of previous births, placenta previa, urinary tract infection, hospital length of stay, HIV testing, NICU admission, breastfeeding and WIC participation[64 65]. This study and prior studies found variation in validation measurements across indicators, with sensitivity consistently performing better than PPV. Findings from validation studies will contribute to the evidence base used to support the utilization of PRAMS for public health surveillance, research and planning.

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[69] PRAMS Model Protocol 2018 - 7 Analysis. https://www.cdc.gov/prams/methodology.htm#zip

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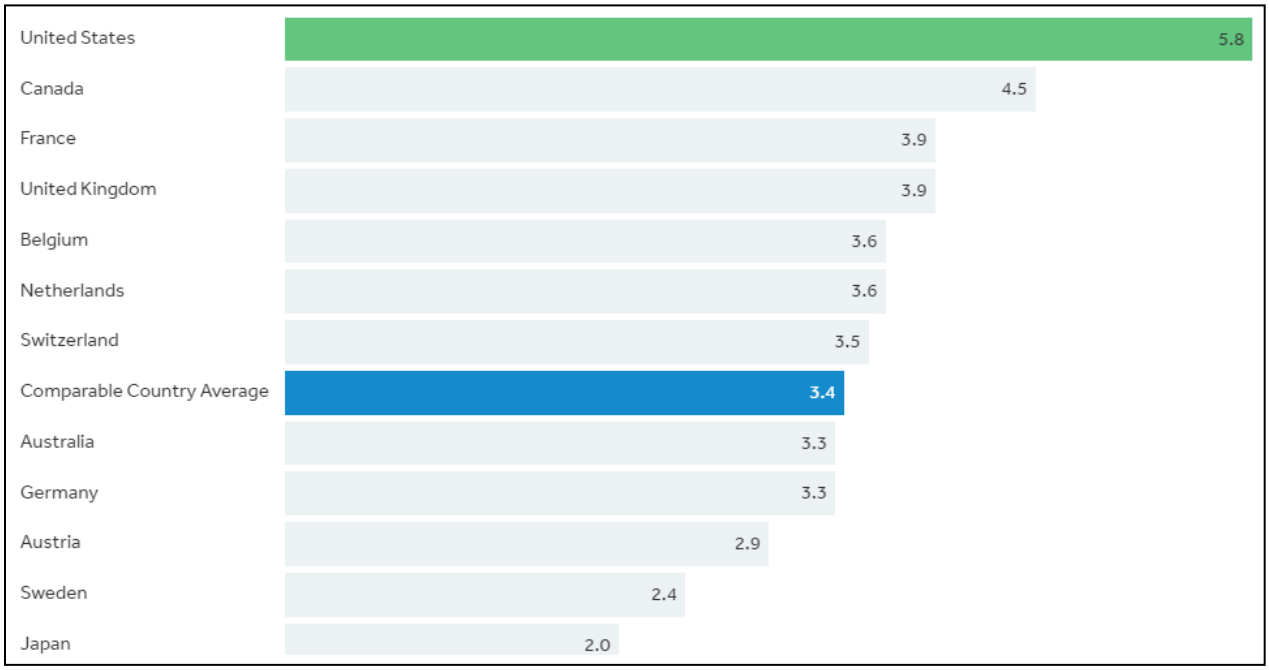
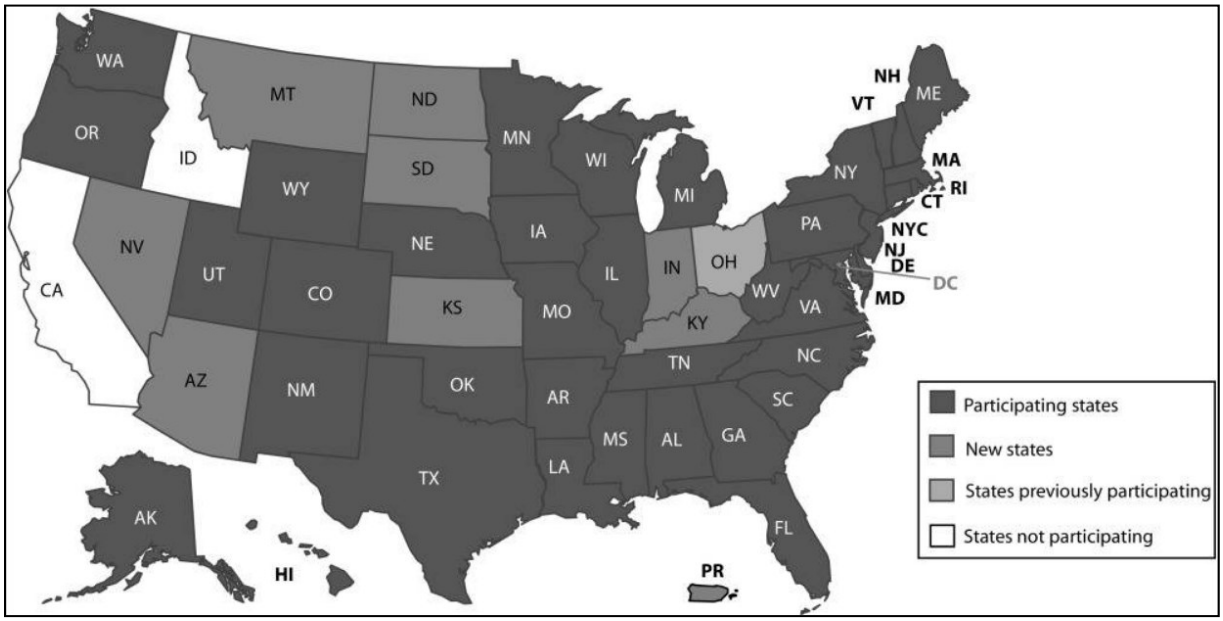
Appendices

Appendix 1: Infant mortality per 1,000 live births, 2017



Source: Kamal R, Hudman J, McDermott D. What do we know about infant mortality in the U.S. and comparable countries? Peterson-KFF Health System Tracker. October 2019. https://www.healthsystemtracker.org/chart-collection/infant-mortality-u-s-compare-countries/#item-)

Appendix 2: Participating States: Pregnancy Risk Assessment Monitoring System (PRAMS), United States, 2017



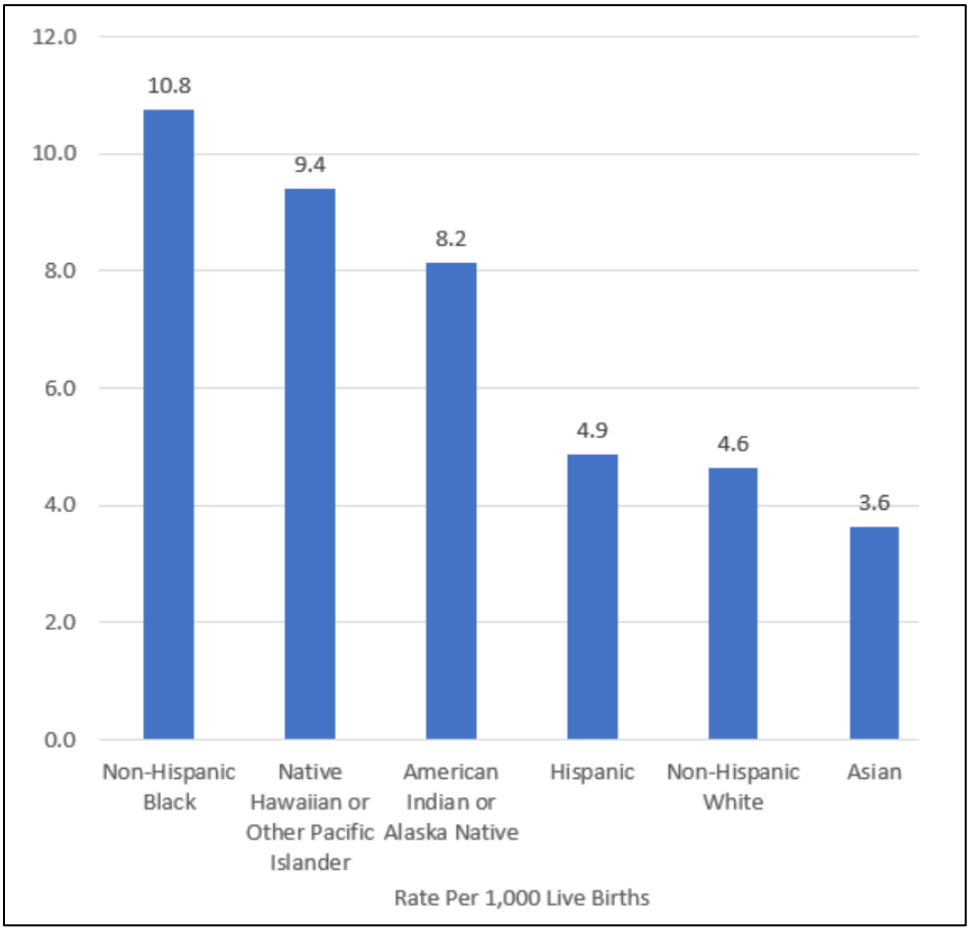
Source: Shulman HB, D'Angelo DV, Harrison L, et al. The Pregnancy Risk Assessment Monitoring System (PRAMS): Overview of Design and Methodology. *Am J Public Health*. 2018;108(10), 1305-1313. https://www-ncbi-nlm-nih-gov.proxy1.library.jhu.edu/pmc/articles/PMC6137777/#bib2

Appendix 3: PRAMS Revision Years

PRAMS Revision	Year
Phase 1 (Pilot)	1988-1989
Phase 2	1990-1995
Phase 3	1996-1999
Phase 4	2000-2003
Phase 5	2004-2008
Phase 6	2009-2011
Phase 7	2012-2015
Phase 8	2016 - Present

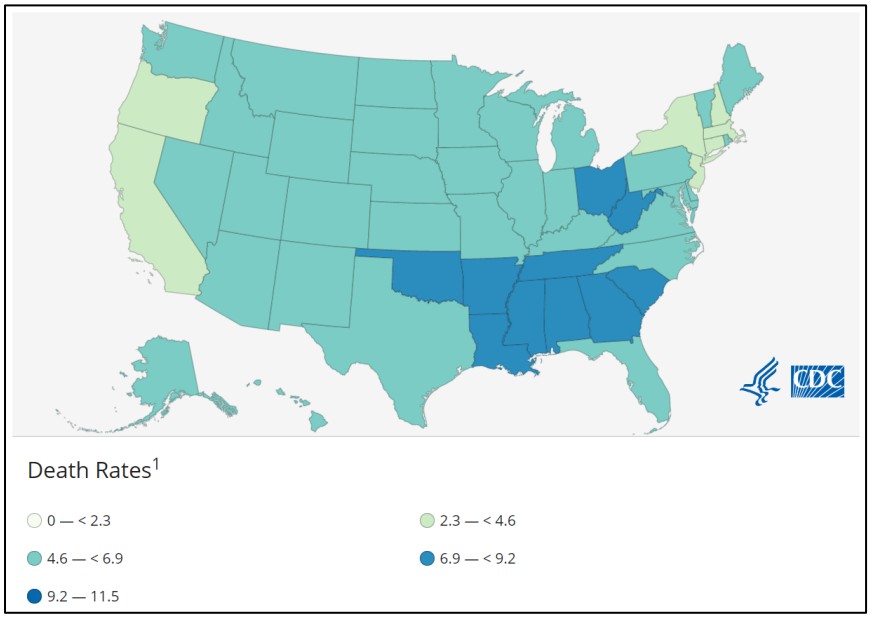
Source: PRAMS Questionnaires. Centers for Disease Control and Prevention. May 2018. https://www.cdc.gov/prams/questionnaire.htm#questions

Appendix 4: Infant Mortality Rates by Race and Ethnicity, 2018



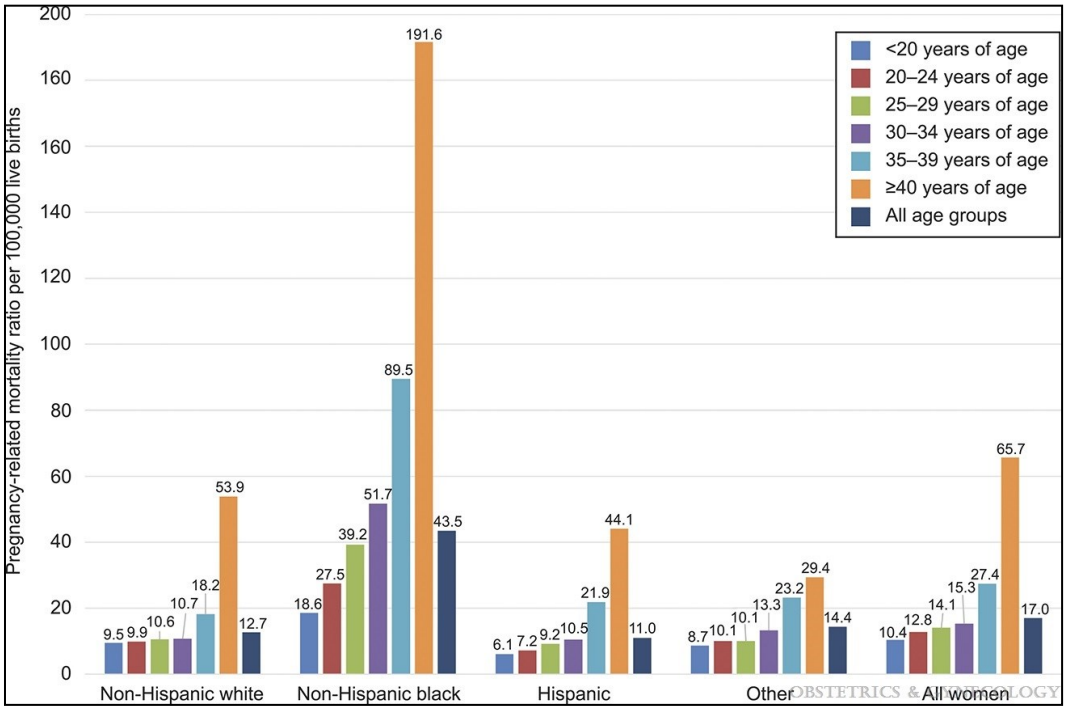
Source: Reproductive Health: Infant Mortality. Centers for Disease Control and Prevention. September 2020. https://www.cdc.gov/reproductivehealth/maternalinfanthealth/infantmortality.htm

Appendix 5: Infant Mortality Rates by State, 2018



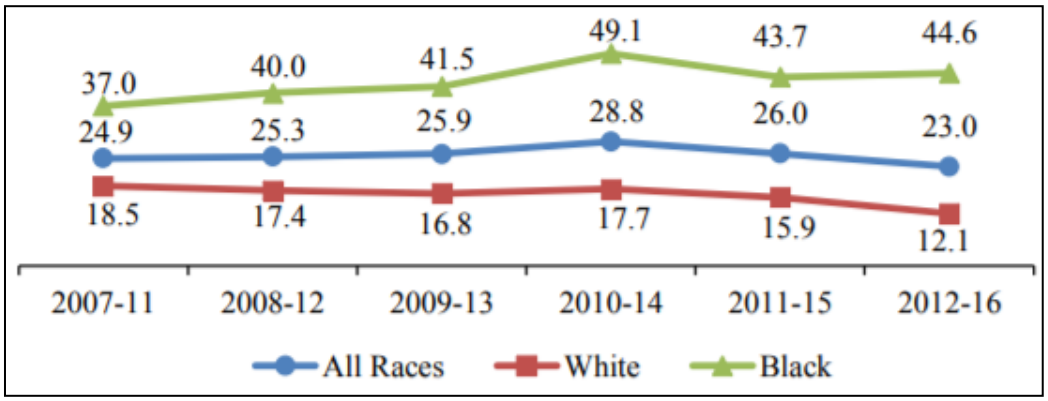
Source: Reproductive Health: Infant Mortality. Centers for Disease Control and Prevention. September 2020. https://www.cdc.gov/reproductivehealth/maternalinfanthealth/infantmortality.htm

Appendix 6: Pregnancy-Related Mortality in the United States, 2011–2013



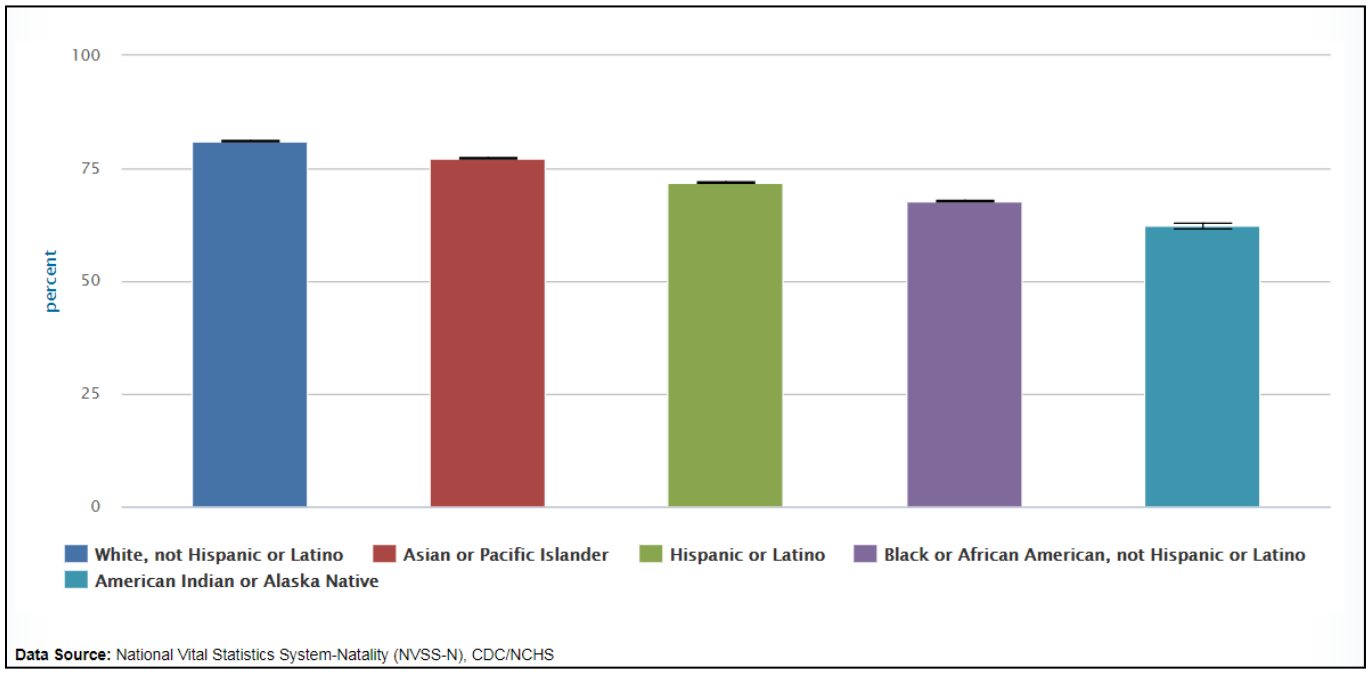
Source: Creanga, AA, Syverson C, Seed, K, et al. Pregnancy-Related Mortality in the United States. *Obstetrics & Gynecology*. 2017;130(2), 366-373. https://journals.lww.com/greenjournal/fulltext/2017/08000/Pregnancy_Related_Mortality_in_the_United_States,.15.aspx

Appendix 7: Five Year Rolling Average, Maternal Mortality Rate by Race, Maryland, 2007-2016



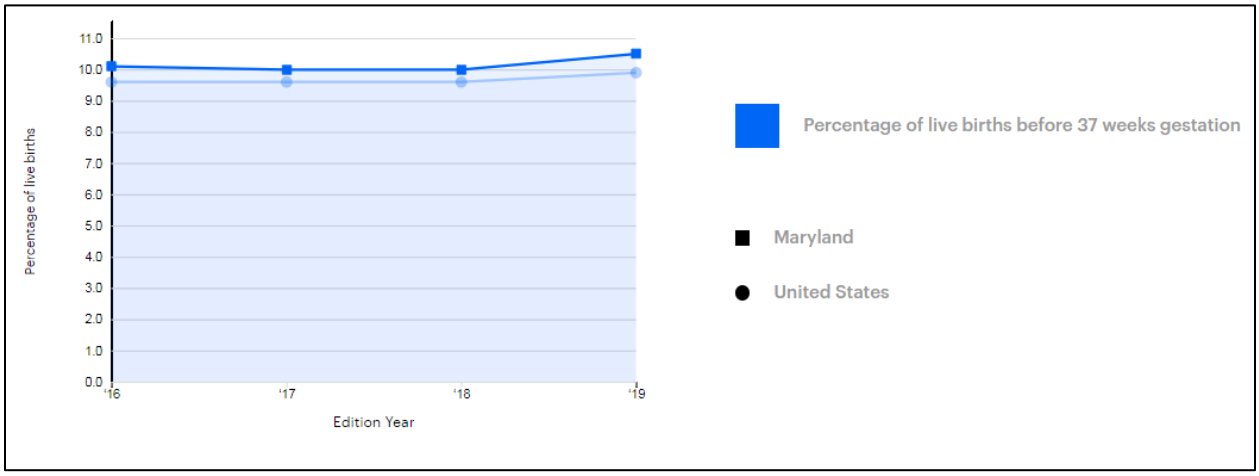
Source: Maryland Maternal Mortality Review 2018 Annual Report. Maryland Department of Health. 2018. http://healthymaryland.org/wp-content/uploads/2019/01/Health-General-Article-%C2%A713-1207-2018-Annual-Report-Maryland-Maternal-Mortality-Review.pdf

Appendix 8: Disparities Details by Race and Ethnicity for 2018 - Pregnant women receiving early and adequate prenatal care



Source: Disparities Details by Race and Ethnicity for 2018. Office of Disease Prevention and Health Promotion: HealthyPeople. 2020. https://www.healthypeople.gov/2020/data/disparities/detail/Chart/4834/3/2018

Appendix 9: Preterm Birth, Maryland, United States



Source: Health of Women and Children: Preterm Birth. United Health Foundation: America's Health Rankings. 2020. https://www.americashealthrankings.org/explore/health-of-women-and-children/measure/pretermbirth_MCH/state/MD

Appendix 10: Maternal Age in Years

	Range	Mean	Missing
PRAMS	20.27, 55.61	34.78	43
Birth Certificate	20.27, 55.61	34.74	0

Source: Author's calculation

Appendix 11: Maternal Nutrition – Mother's BMI

	Range	Mean	Missing
PRAMS	10.38, 64.48	26.5508	172
Birth Certificate	14.90, 63.23	26.9369	67

Source: Author's calculation

Appendix 12: First Prenatal Care Visit in Weeks

	Range	Mean	Missing
PRAMS	-6.99, 57.71	12.33	377
Birth Certificate	-6.99, 45.29	12.32	340

Source: Author's calculation

Appendix 13: Maternal Health – Gestational Hypertension

	Yes	No	Missing
PRAMS	328	1,865	34
Birth Certificate	274	1,952	1

Source: Author's calculation

Appendix 14: Maternal Health – Gestational Diabetes

	Yes	No	Missing
PRAMS	227	1,964	36
Birth Certificate	181	2,045	1

Source: Author's calculation

Appendix 15: Reproductive History – Previous Live Births

	Yes	No	Missing
PRAMS	1,312	896	19
Birth Certificate	1,356	871	0

Source: Author's calculation

Appendix 16: Reproductive History – Previous Cesarean Delivery

	Yes	No	Missing
PRAMS	297	1,930	0
Birth Certificate	391	922	914

Source: Author's calculation

Appendix 17: Cigarette Smoking – Pre-pregnancy

	0	<1	1 to 5	6 to 10	11 to 20	21 to 40	41≤	Missing
PRAMS	1965	32	80	73	63	13	1	0
Birth Certificate	2034	0	56	61	57	9	1	9

Source: Author's calculation

Appendix 18: Cigarette Smoking – Last 3 Months of Pregnancy

	0	<1	1 to 5	6 to 10	11 to 20	21 to 40	41≤	Missing
PRAMS	2097	17	63	41	8	0	1	0
Birth Certificate	2124	0	45	40	9	0	0	8

Source: Author's calculation

Appendix 19: Maternal Health Insurance

	Medicaid	Private Insurance	Self	Champus/ Tricare	Other	Missing
PRAMS	515	1,225	91	75	177	144
Birth Certificate	897	1,170	78	49	24	9

Source: Author's calculation

Appendix 20: Document Review References

No.	Reference	Category
1	PRAMS. Centers for Disease Control and Prevention. February 2020. https://www.cdc.gov/prams/index.htm	CDC
2	Frequently Asked Questions About PRAMS. Centers for Disease Control and Prevention. February 2019. https://www.cdc.gov/prams/about/prams-faq.htm	CDC
3	Methodology. Centers for Disease Control and Prevention. December 2019. https://www.cdc.gov/prams/methodology.htm	CDC
4	Ahluwalia IB, Helms K, Morrow B. Assessing the Validity and Reliability of Three Indicators Self-Reported on the Pregnancy Risk Assessment Monitoring System Survey. *Public Health Reports*. 2013;126(6), 527-536. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3804096/	Journal
5	PRAMS Questionnaires. Centers for Disease Control and Prevention. May 2018. https://www.cdc.gov/prams/questionnaire.htm#questions	CDC
6	PRAMS Special Projects. Centers for Disease Control and Prevention. March 2018. https://www.cdc.gov/prams/special-projects/index.htm	CDC
7	Selected 2016 through 2017 Maternal and Child Health (MCH) Indicators. Centers for Disease Control and Prevention. January 2020. https://www.cdc.gov/prams/prams-data/mch-indicators.html	CDC
8	For Researchers. Centers for Disease Control and Prevention. January 2020. https://www.cdc.gov/prams/prams-data/researchers.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fprams%2Fresearchers.htm	CDC
9	PRAMS Working Group. CDC PRAMS Guidelines For Proposals To Conducting Multi-State Analyses. Centers for Disease Control and Prevention. February 2010. https://www.cdc.gov/prams/pdf/researchers/PRAMSProposal_guidelines_2010.pdf	CDC
10	PRAMS Data to Action Success Stories. Centers for Disease Control and Prevention. February 2019. https://www.cdc.gov/prams/state-success-stories/data-to-action-success.html	CDC
11	Participating PRAMS Sites. Centers for Disease Control and Prevention. July 2020. https://www.cdc.gov/prams/states.htm	CDC
12	Pregnancy Risk Assessment Monitoring System (PRAMS) Report on CDC's Winnable Battles: Collecting Data in Order to Improve the Health of Mothers and Infants. Centers for Disease Control and Prevention. August 2013. https://www.cdc.gov/prams/pramsreport.html	CDC
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14	Maryland PRAMS: PRAMS for Researchers. Maryland Department of Health. https://phpa.health.maryland.gov/mch/Pages/prams_researchers.aspx	Health Dept.
15	Maryland PRAMS: Methodology. Maryland Department of Health. June 2017. https://phpa.health.maryland.gov/mch/Pages/prams_methodology.aspx	Health Dept.
16	Maryland PRAMS: Survey. Maryland Department of Health. July 2017. https://phpa.health.maryland.gov/mch/Pages/prams_survey.aspx	Health Dept.
17	Prevention and Health Promotion Administration, Vital Statistics Administration (VSA), PRAMS Team. Maryland PRAMS Report 2017 Births. Maryland Department of Health. April 2019. https://phpa.health.maryland.gov/mch/Documents/MD%20PRAMS%202017%20Births%20Annual%20Report.pdf	Health Dept.
18	Pregnancy Risk Assessment Monitoring System. NYC Health. https://www1.nyc.gov/site/doh/data/data-sets/pregnancy-risk-assessment-monitoring-system.page	Health Dept.
19	What is PRAMS 2012 Update. NYC Health. https://www1.nyc.gov/assets/doh/downloads/pdf/ms/PRAMSintro.pdf	Health Dept.

20	Pregnancy Risk Assessment Monitoring System. Ohio Department of Health. https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/pregnancy-risk-assessment-survey-prams	Health Dept.
21	PRAMS Questionnaires. Ohio Department of Health. July 2019. https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/pregnancy-risk-assessment-survey-prams/questionnaires/	Health Dept.
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24	PRAMS 2015 Surveillance Report – Alabama. Bureau of Family Health Services. May 2019. https://www.alabamapublichealth.gov/prams/assets/prams2015.pdf	Health Dept.
25	Hawaii Pregnancy Risk Assessment Monitoring System (PRAMS). State of Hawaii, Department of Health. https://health.hawaii.gov/fhsd/home/hawaii-pregnancy-risk-assessment-monitoring-system-prams/	Health Dept.
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30	Shulman HB, D'Angelo DV, Harrison L, et al. The Pregnancy Risk Assessment Monitoring System (PRAMS): Overview of Design and Methodology. *Am J Public Health*. 2018;108(10), 1305-1313. https://www-ncbi-nlm-nih-gov.proxy1.library.jhu.edu/pmc/articles/PMC6137777/#bib2	Journal
31	Shulman HB, Gilbert BC, Lansky A. The Pregnancy Risk Assessment Monitoring System (PRAMS): Current Methods and Evaluation of 2001 Response Rates. *Public Health Reports*. 2006;121(1), 74-83. https://www-ncbi-nlm-nih-gov.proxy1.library.jhu.edu/pmc/articles/PMC1497801/	Journal
32	Ghandour, RM. The Pregnancy Risk Assessment Monitoring System (PRAMS): Current Strengths and Opportunities for Growth", *American Journal of Public Health*. October 2018;108(10), 1303-1304. https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2018.304662	Journal
33	Grigorescu VI, D'Angelo DV, Harrison LL, et al. Implementation Science and the Pregnancy Risk Assessment Monitoring System. *Journal of Women's Health*. December 2014;23(12), 989-994. https://www-ncbi-nlm-nih-gov.proxy1.library.jhu.edu/pmc/articles/PMC4267766/	Journal
34	Ahluwalia, IB, Harrison L, Simpson P, et al. Pregnancy Risk Assessment Monitoring System and the W.K. Kellogg Foundation Joint Project to Enhance Maternal and Child Health Surveillance: Focus on Collaboration. *Journal of Women's Health*. April 2015;24(4), 257-260. https://www-liebertpub-com.proxy1.library.jhu.edu/doi/10.1089/jwh.2015.5260	Journal
35	Dozier AM, Brownell E, Guido J, et al. Adapting the Pregnancy Risk Assessment Monitoring Survey to Enhance Locally Available Data: Methods. *Maternal and Child Health Journal*. August 2013;18, 1196-1204. https://link-springer-com.proxy1.library.jhu.edu/article/10.1007/s10995-013-1350-6	Journal
36	Deputy NP, Sharma AJ, Bombard JM, et al. Quality of Maternal Height and Weight Data from the Revised Birth Certificate and Pregnancy Risk Assessment Monitoring System. *Epidemiology*.	Journal

	January 2019;30(1), 154-159. http://ovidsp.dc2.ovid.com.proxy1.library.jhu.edu/sp-4.02.1a/ovidweb.cgi?T=JS&PAGE=fulltext&D=ovft&AN=00001648-201901000-00019&NEWS=N&CSC=Y&CHANNEL=PubMed	
37	Dietz P, Bombard J, Mulready-Ward C, et al. Validation of Self-reported Maternal and Infant Health Indicators in the Pregnancy Risk Assessment Monitoring System. *Maternal and Child Health Journal*. April 2014;18, 2489-2498. https://link-springer-com.proxy1.library.jhu.edu/article/10.1007%2Fs10995-014-1487-y	Journal
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39	Beck LF, Morrow B, Lipscomb LE, et al. Prevalence of Selected Maternal Behaviors and Experiences, Pregnancy Risk Assessment Monitoring System (PRAMS), 1999. *Surveillance Summaries*. April 2002,51(2), 1-26. https://www.cdc.gov/mmwR/preview/mmwrhtml/ss5102a1.htm	Journal
40	Kotelchuck M. Pregnancy Risk Assessment Monitoring Systems (PRAMS): Possible New Roles for a National MCH Data System. Public Health Reports. February 2006;121(1), 6-10. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1497800/	Journal
41	Williams LM, Morrow B, Lansky A, et al. Surveillance for Selected Maternal Behaviors and Experiences Before, During, and After Pregnancy: Pregnancy Risk Assessment Monitoring System (PRAMS), 2000. *Surveillance Summaries*. November 2003,52(11), 1-14. https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5211a1.htm	Journal
42	Phares TM, Morrow B, Lansky A, et al. Surveillance for Disparities in Maternal Health-Related Behaviors---Selected States, Pregnancy Risk Assessment Monitoring System (PRAMS), 2000-2001. *Surveillance Summaries*. July 2004,53(4), 1-13. https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5304a1.htm	Journal
43	Vermont Pregnancy Risk Assessment Monitoring System (PRAMS). Vermont Department of Health. November 2020. https://www.healthvermont.gov/health-statistics-vital-records/population-health-surveys-data/pregnancy-risk-assessment-and	Health Dept.
44	PRAMS Model Protocol 2018 - 1 Introduction. https://www.cdc.gov/prams/methodology.htm#zip	Protocol
45	PRAMS Model Protocol 2018 - 2 Goals. https://www.cdc.gov/prams/methodology.htm#zip	Protocol
46	PRAMS Model Protocol 2018 - 3 Staffing. https://www.cdc.gov/prams/methodology.htm#zip	Protocol
47	PRAMS Model Protocol 2018 - 4 Sampling. https://www.cdc.gov/prams/methodology.htm#zip	Protocol
48	PRAMS Model Protocol 2018 - 5 Data Collection. https://www.cdc.gov/prams/methodology.htm#zip	Protocol
49	PRAMS Model Protocol 2018 - 6 Data Management. https://www.cdc.gov/prams/methodology.htm#zip	Protocol
50	PRAMS Model Protocol 2018 - 7 Analysis. https://www.cdc.gov/prams/methodology.htm#zip	Protocol
51	PRAMS Model Protocol 2018 - 8 Authorship. https://www.cdc.gov/prams/methodology.htm#zip	Protocol
52	PRAMS Model Protocol 2018 - 9 Timetable. https://www.cdc.gov/prams/methodology.htm#zip	Protocol
53	PRAMS Model Protocol 2018 - 10 Human Subjects. https://www.cdc.gov/prams/methodology.htm#zip	
54	PRAMS Model Protocol 2018 - 11 Evaluation. https://www.cdc.gov/prams/methodology.htm#zip	Protocol
55	PRAMS Model Protocol 2018 - 12 Glossary. https://www.cdc.gov/prams/methodology.htm#zip	Protocol

Source: Author's construction

Appendix 21: Interview Guide

Randomized Selection

There were 4 steps in the randomized selection of key stakeholders:

1. All state PRAMS Coordinators and Title V MCH Directors were listed as key stakeholders (n=99)
2. For each key stakeholder, the Excel RAND function was used to return a random number greater than or equal to 0 and less than 1 with an even distribution
3. The Excel RANK function was used to return the rank of the randomized numbers
4. Using the prioritized ranking, the list of state PRAMS Coordinators and Title V MCH Directors were categorized into the following three recruitment groups.

Group 1		Group 2		Group 3	
PRAMS Coordinators	**Title V MCH Directors**	**PRAMS Coordinators**	**Title V MCH Directors**	**PRAMS Coordinators**	**Title V MCH Directors**
Alaska	Arkansas	Alabama	Alaska	Delaware	Alabama
Arkansas	Colorado	Arizona	District of Columbia	Georgia	Arizona
Florida	Georgia	Connecticut	Hawaii	Iowa	Connecticut
Hawaii	Illinois	District of Columbia	Indiana	Kentucky	Delaware
Illinois	Iowa	Kansas	Kentucky	Louisiana	Florida
Indiana	Kansas	Mississippi	Maine	Maine	Louisiana
New Hampshire	Mississippi	Montana	Massachusetts	Massachusetts	Maryland
North Dakota	Nevada	Nebraska	Missouri	Maryland	Minnesota
Oklahoma	New Jersey	New Mexico	North Carolina	Michigan	Montana
Oregon	New York	New York	Oklahoma	Minnesota	Nebraska
Pennsylvania	Oregon	New York City	Pennsylvania	Missouri	New Hampshire
Rhode Island	Puerto Rico	Puerto Rico	Texas	Nevada	New Mexico
South Carolina	Rhode Island	South Dakota	Utah	New Jersey	North Dakota
Washington	Vermont	Vermont	Virginia	North Carolina	South Carolina
Wyoming	Wisconsin	Wisconsin	West Virginia	Tennessee	South Dakota
				Texas	Tennessee
				Utah	Washington
				Virginia	Wyoming
				West Virginia	

Recruitment Efforts

The groups were recruited sequentially starting with group 1. Recruitment letters were emailed to group 1 to solicit participation for the study. The recruitment letter included an overview of the study and a request for study participation. Stakeholders in group 1 were sent two follow-up emails requesting their participation in the study, for a total of three recruitment emails. After three weeks, the study indicated non-respondents as "decline to participate" and sent recruitment letters to the next group of stakeholders. This recruitment process was continued until the desired sample size and data saturation were reached.

Recruitment Letter

Subject: PRAMS Research Study – Participants Needed

Dear PRAMS Stakeholder,

My name is Phylicia McCalla and I am a Doctor of Public Health (DrPH) student at Johns Hopkins University. This email is to invite you to participate in a research study to evaluate the strengths and limitations of the Pregnancy Risk Assessment Monitoring System (PRAMS). You have been identified as a key stakeholder because of your experience administrating the PRAMS survey, managing a local PRAMS program, or using the PRAMS data for various administrative and reporting purposes. Your insight and perspective will be used to help validate PRAMS as a public health surveillance system for pregnancy risk.

Participation in this research study is voluntary. Study data will be collected during a 30-minute, audio stakeholder interview. During this interview, you may be asked questions about your perspective of PRAMS, its processes, accomplishments, and challenges. Interview responses will be de-identified to protect the privacy of study participants.

If you are interested in participating in the research study or have questions, please reply to the study's student investigator, Phylicia McCalla, at pmccall3@jhmi.edu.

Thank you very much for your consideration.

Structured Interview Consent

Hello, my name is Phylicia McCalla and I am from Johns Hopkins' Bloomberg School of Public Health, Department of Health Policy and Management. Today, I would like to talk to you about a research study on the Pregnancy Risk Assessment Monitoring System (PRAMS). The study aim is to evaluate the strengths and limitations of PRAMS as a pregnancy surveillance system by assessing its system attributes. We asked you to join this study because you have been identified as a key stakeholder that can share your perspective of and your unique experience with PRAMS. Participation in the research study is voluntary. Your decision will not affect your employment rights or benefits.

If you say yes, we will ask you to participate in a recorded audio interview. During this interview, you may be asked questions about your perspective of PRAMS, its processes, accomplishments, and challenges. It will take no more than 30 minutes to complete this interview.

You do not have to answer all the questions and you may stop at any time. There is a risk that someone outside the study will see your information. We will do our best to keep your information safe by securing data on a secured server, using an encrypted device, and removing identifying information before it is shared. If we share your information with other researchers, they will use the same protections.

You will receive no direct benefit from this study. We will use the information you provided to inform the research study and validate PRAMS as a public health surveillance system for pregnancy risk.

There is no payment if you join this study.
Do you have any questions? You may ask me now or contact me at 646-417-2355 regarding questions or problems with this study. You may contact the study's Principal Investigator (PI) Darrell J. Gaskin, PhD at 443-287-0306. Additionally, you may contact the Institutional Review Board, which approved this study, about any problems or concerns at:

Address:	Johns Hopkins Bloomberg School of Public Health
	615 N. Wolfe Street, Suite E1100
	Baltimore, MD 21205
Telephone:	410-955-3193
Toll Free:	1-888-262-3242
Fax:	410-502-0584
E-mail:	JHSPH.IRBOffice@jhu.edu

May I begin?

Interview Questions (n=20)

Sensitivity

Definition: The ability of the surveillance system to detect the proportion of cases of a health-related event and the ability to monitor changes in the number of events over time.

Questions:

1. How willing are respondents to accurately report their behaviors and experiences on the PRAMS survey?
2. How would you describe the ability of persons to understand the questions and correctly identify their health condition/status?
3. How does your state validate the data collected by the surveillance system?
4. How does your state validate that survey responses are coming from the intended source, being sampled mothers?
5. In your professional experience, can PRAMS truly estimate the proportion of the total number of cases in the population under surveillance?

Positive Predictive Value (PPV)

Definition: Positive predictive value (PVP) is the proportion of reported cases that actually have the health-related event under surveillance.

Questions:

1. Have there been investigations to confirm health-related behaviors and experiences reported through PRAMS? If so, please explain.
2. What data sources have been used to confirm reports of health-related behaviors and experiences identified by PRAMS?
3. In your experience, has PRAMS identified false positive reports?
4. Describe how PRAMS data is used to direct public health resources in your state.

Timeliness

Definition: Timeliness reflects the speed between steps in a public health surveillance system.

Question:

1. The length of time from when PRAMS data is collected until it is made available is approximately one year. Is this level of timeliness satisfactory for effective control efforts, prevention and program planning? Please explain.

Stability

Definition: Stability refers to the reliability (i.e., the ability to collect, manage, and provide data properly without failure) and availability (the ability to be operational when it is needed) of the public health surveillance system.

Questions:

1. Have there been scheduled down times for the PRAMS system? If so, how frequently?
2. Have there been unscheduled down times for the PRAMS system? If so, how frequently?
3. To the best of your knowledge, what is the cost and time involved with repairing the PRAMS system?
4. To the best of your knowledge, what is the percentage of time the system is fully operational?
5. In your experience, does the surveillance system have adequate, dedicated resources to support the reliability and availability of data? Please explain.

Remaining Attributes

Do you agree or disagree with the following statements? Please explain why you agree or disagree.

1. Simplicity – PRAMS is a complex and resource-intensive surveillance system.
2. Flexibility – PRAMS is a flexible surveillance system that can accommodate new health-related events, new demands, and changes in design or technology.
3. Data Quality – PRAMS is able to maintain high data quality and continues to enhance the validity of data collected by the surveillance system.
4. Acceptability – PRAMS has high acceptability and willingness of persons to participate in the surveillance system, including persons that operate the system and persons that participate in the survey.
5. Representativeness – PRAMS is generalizable and has the ability to accurately describe health-related behaviors and experiences over time and its distribution in the population by place and person.

Appendix 22: Key Themes and Stakeholder Interview Quotes

Attribute	Key Themes	Stakeholder Quotes
Simplicity	Program Structure	[1] *"I'm not sure if you're aware of just how complex PRAMS is… it is very involved… I'm constantly amazed at the quantity and quality of work that a very small but mighty team does."* [2] *"I would say it is complex and that it is an operational plan that has many moving parts that are all happening at the same time. It requires the collaboration of a lot of different public health partners, whether that's Vital Records, operational teams, epidemiologist, etc."* [3] *"It requires more resources than what CDC allocates to us."* [4] *"There are multiple components that go into the overall PRAMS function…various resources along each step of the way that must be utilized to make sure it's all working properly"* [5] *"I think the protocol can be looked at, revisited, revised, so that it doesn't have to be done in such a complex manner. I think sometimes things are made to be a little too complex and are too rigid."* [6] *"There is a process already in place. They have a schedule and a timeline that they have to adhere to their standards, especially because this is something that is conducted between all the states."*
	Staff Training Requirements	[7] *"With the multimodal data collection approach, it requires a lot of different resources…requires everything that goes along with running a mail survey operation, as well as a phone survey operation, which is very different and requires different skill sets and equipment…it has a lot of different people involved in making sure that the surveillance system functions."*

Flexibility	Data Collection & Management	[8] *"There's a lot of processes happening simultaneously in terms of the data collection. So, we may have multiple batches in different stages at any given time…making sure that you're tracking what batches or what stage of what needs to be done and following through on our protocols…it is time intensive."* [9] *"It's dual mode, it's mail and phone…both modes create their own challenges. We're in the process of adding a web mode and so we will be a tri-mode survey. PRAMS is totally complex and resource intensive."* [10] *"On average, our staff are able to find three to four contact numbers for each individual that makes it to phone, so that is 15 calls times three or four numbers times however many moms are in a batch…"* [11] *"Everything is programmed in PIDS, the PRAMS Integrated Data Collection System. It is very, very easy to enter data, to prepare mailings, to follow up on phone calls."*
	Data Analysis	[12] *"All the nuance of [PRAMS] is really hard to convey and to get people to understand what your data actually reflects."* [13] *"I think that our partners at the survey center, they support PRAMS. They think it's really important, but they find it to be much more complex and more work than other surveys that they run. And I think, to some extent, that's appropriate because of the extra protections we have with the population that we serve."*
	System Tailored Design & Methodology	[14] *"I think there needs to be more of a balance because I think the attention and focus is placed on states collecting data exactly the same way…there are ways I think that the states could individually come up with ways to let PRAMS be more nimble, more flexible. We've got email address for a large majority of our samples each month…we could implement something like texting or sending a QR code out for the survey. I just don't think PRAMS should be primarily mail anymore."* [15] *"Some PRAMS sites have additional funds where they can respond…they can figure out technological workarounds…Some states have been asking about COVID since June… it really depends if that state has additional money and people to work around the limitations of national PRAMS. We are not. So, we're stuck until CDC could provide these things…Some states have the flexibility so that the built-in limitations of the large federal program don't affect them as much."*
	Technology	[16] *"I think the potential is there for it to be flexible…our state was originally supposed to be in the pilot of the web implementation of PRAMS… and that was over three year ago, and it still hasn't happened."* [17] *"I think if we could use more systems and take advantage of the technology…we'd be much better off, and we can be flexible, and we could gather information much quicker."*

		[18] *"I think when it comes to technology, I don't think it's a very flexible project…we've been promised a web survey for quite a while. It hasn't come to fruition yet."* [19] *"We will be looking forward to adopting a web-based modality because we anticipate that would take off a large amount of the burden of individuals who choose to participate by mail. And so, there would be less of a need to prepare mailers and do data entry once those hard copies came in. So, there's quite a lot of benefits to having that web-based survey."*
	Questionnaire Customization	[20] *"The survey is very flexible in terms of being able to add state added questions or to accommodate a state's individual need or issues that are occurring in a specific state. It can also be easily accommodating to the entire group of states that participate in PRMAS to collect data or information on new and emerging issues, such as the opioid epidemic."* [21] *"We've been able to add maternal mental health questions to the survey. So that's been very valuable because in our needs-assessment processes for the Title V Maternal and Child Health grant, maternal mental health has risen up as literally the top priority for women of childbearing age…So I believe that PRAMS does provide that flexibility."* [22] *"It would be nice to be more flexible, to enact things faster…an example being the pandemic… it would have been nice to have more flexibility to add questions for emergency problems faster."* [23] *"I don't think it's that nimble to add questions in real time. I think it takes us a little bit of time, to see that there's new trends in pregnancy, for instance, use of marijuana."*
	PRAMS Questionnaire Revision	[24] *"Phase eight started in 2016. So, the questions are different than the 2015 questions…as the way we talk about a topic or the way we think about a topic changes, the survey can change to reflect that. So that's the strength of the survey. We can add supplements as needed and as appropriate."* [25] *"We haven't updated the questionnaire since 2014-2015. So, a lot of us are asking the same questions over multiple years."*
	Supplements	[26] *"I think that PRAMS is doing much better at being more responsive to emerging health issues with a lot of the special supplements that we've been able to add in the past few years, specifically related to opioid use and right now we're doing a COVID supplement. So, we're able to gather data quickly on emerging health issues."* [27] *"We've already implemented four supplements, one for Zika, one for disaster, one for opioids, and the current one if for Covid-19. And it is very easy to add the questions to the regular PRAMS mailing and in the PIDS system."* [28] *"The Zika supplement… PRAMS was able to respond to it with targeted extra questions that really helped, especially sites like Puerto Rico, figure out what's going on."*

		[29] *"We added a supplement to our 2020 data collection that was totally state initiated. And we were lucky we were able to pivot at the last moment to add questions related to Covid. We've been asking those since the beginning of 2020 births. CDC did develop its own Coronavirus supplement, but I don't think it was available until October. So, a good five months after Coronavirus really started affecting our populations."* [30] *"We use supplements…CDC comes out with a supplement like the opioid or disability supplement, or even like the Covid supplement…that definitely serves us really well. We did a marijuana supplement in 2017…that marijuana supplement was, I think, beneficial. I think it caught a lot of people's eyes, in terms of adult marijuana use, and then just marijuana use among pregnancy women, or breastfeeding women. So yeah, I think the flexibility of that is really beneficial."* [31] *"We've had the ability to add different supplements. With that being said, that is not without cost. There is a great amount of effort that is put into applying for these opportunities, training staff in asking those new questions and any additional work that needs to be done so those questions can be added to PIDS."* [32] *"Although its costly to add questions, I do believe PRAMS is flexible and does provide an opportunity to more or less fit the survey to meet the needs or demands of changing events."*
Data Quality	Quality Control	[33] *"It has a standard established manner for surveying and it provides quality information that we can use to draw conclusions and to inform programs."* [34] *"As part of the protocol, there's quality control. For example, there is data cleaning and editing. We make verification of the data entry…and make sure that the data is correctly entered in the system. And then CDC cleans and weighs the data. I'm in charge of monitoring 10% of the interviews to make sure the interviewer is reading correctly the questionnaire and following the script to makes sure everything is correctly asked. CDC has their own batch checking procedures for editing and data entry verification."* [35] *"I do feel that the CDC has given us a good amount of tools and technical assistance…We do consistent human subjects training, and have consistent communication with our team and CDC around any issues that may arise at any spectrum of the data collection process."* [36] *"I think the questions that are used are well-designed. I think the protocols are well designed and clear. That allows us to consistently collect high quality data…We continue to apply best practices in survey research."* [37] *"I think that the process of gathering, maintaining, verifying, securing, weighting, the protocols around reporting…all that are really solid."* [38] *"I think that PRAMS does a good job of collecting the data. And it is very informative for what we do at the health department and what we can share*

		with organizations and agencies to help mothers and parents and their families." [39] *"Every time we do a new phase, we're doing a phase evaluation, and we are looking at quantitative as well as qualitative commentary. So, there's a lot of QA going on. If it looks like moms are not understanding the question because of the comments they are making, then that questions gets tweaked."*
	IRB Approval	[40] *"I do believe that PRAMS collects high quality data. I do think that is attributed to how prescriptive we are and the fact that we have two IRBs that we kind of have to answer to."* [41] *"I think the data is of good quality and they do continue to maintain validity…reviews are in place by different IRBs."*
	Data Source	[42] *"I think it goes back to…do women feel comfortable honestly answering the PRAMS questions. So, you're relying on someone's self-report and you're relying on someone's integrity to tell the truth and if they don't, then that's going to influence the validity of the data that you collect. I think to the degree that an anonymous self-report can be used to collect data. It's probably about as valid as it can be. But it's not going to be as valid as other types of data that are collected in more controlled methods."* [43] *"It's high quality. You can trust the responses that you're getting to know that it was asked correctly."*
	Response Rate Threshold & Sample Sizes	[44] *"Each state is required to maintain a specific threshold of a response rate in order to ensure validity of the survey."* [45] *"The PRAMS project is always striving to make sure that we're adhering to best practices, collecting the most reliable data that we can, ensuring states have the resources that they need to accomplish that. Reviewing minimum thresholds to make sure that we're not losing our ability to detect differences in populations."* [46] *"We also know that across the board, all too many types of surveillance systems like this, I've seen decreased response rates for a variety of reasons."*
Acceptability	Respondent Participation	[47] *"I would say our response rates speak for the level of acceptability. I do think that our response rates speak to the strength of our phone interviewing team. Many states may echo this, that there has been a decrease in mail response rate over the years across the nation and across even surveillance systems that use surveys. And so sometimes that personal touch is needed through the phone interview in order to achieve that high response rate and level of acceptability."* [48] *"Although we have seen response rates declining over the last years, we still maintain our minimum thresholds. And so, we still have women who are willing to complete the surveys and share their information."*

		[49] *"Based on the response rate, it seems like moms are interested in responding to the survey. Our response rate increased when we increased it from a $10 reward to a $20 reward…The feedback and the success of the program recently makes me think that moms are satisfied and interested in the survey."* [50] *"We've been able to exceed the CDC response rate threshold, which means that people are still wanting to reply to or respond to the questionnaire."* [51] *"We currently have a response rate that is over the CDC required threshold of 55%. And we have seen over the years an increase of that response rate with regards to participants willingness to answer the questions."* [52] *"I think states who have a real problem with their response might not be able to agree because they have low response rates, or they haven't been reaching the threshold."* [53] *"When you look at the note field of the surveys that we received back, there has been a very positive response among the women we send the survey to."* [54] *"People call in with questions about the survey. When they're like 'I got this packet, what is this?' And as soon as I explain it, they're like 'Oh, yeah, of course, I'm gonna take it.'"* [55] *"I think it's more of an individual acceptability, rather than a population acceptability. Like it's what works for them at this time…I think that the willingness to participate is probably there for a lot of people… but the actual converting a sampled participant to an actual respondent is different."* [56] *"Most people are pretty interested in taking it. It's just a matter of, if they can take it. I feel like sometimes we interview some of the busiest people in the world…with an infant, and then of course, perhaps other children, families, jobs, multiple jobs, all these things."* [57] *"…As long as refusal rates are low for the participates. I would say that's something to monitor, make sure that you're responding to your refusal rates, that they don't get higher than what your state has determined is an acceptable range. And if it is, then I think you can look to see if you have a protocol in place for optimizing response rates."* [58] *"We haven't done a non-response analysis to see for people who don't complete the survey, are we able to get in touch with them, but they're not choosing to complete the survey versus are we not reaching them in the first place."* [59] *"We have widely varying response rates across our strata. We use race-based stratified random sample here in our state. And the response rates, especially in the African American stratum are pretty low…I could speculate about why that is, related to burden of research on that population and distrust of government…I think the challenge is we don't get to hear from those people who don't respond, so it's impossible to know why they don't respond, whether it's because it's not acceptable or whether they just have competing priorities,*

		but those kind of low response rates in some of our populations indicates to me that there may be some issues with accessibility." [60] *"…it requires incentivizing people and providing a reward or an incentive for them to participate. And even then, it takes a lot of follow up… we definitely don't get 100% participation. You have to incentivize. So, I don't think the willingness to participate is as high and I think a lot of people do it just to get the incentive."* [61] *"…given the right incentives and encouragement and the right marketing."*
	Site Participation	[62] *"I think that most of us who operate the system feel very positively about it and are willing to learn how to use it and feel that it's very effective…I would also add end users, like data users, have high confidence in PRAMS."* [63] *"I definitely feel that as far as on our end, for individuals who give the survey, absolutely high acceptability, we have a really strong and wonderful team."* [64] *"People that work for the program, at the phone interviewer level and then also the mail operations, seem to really believe that the questions and the survey are addressing topics of importance."* [65] *"There's a definite interest in how this data can contribute to maternal child health in the state and even more broadly. And so, people professionally really gravitate toward it."*
	Privacy & Confidentiality	[66] *"…someone is on the other end of the phone explaining what this is and how you are protected and how your information is protected."*
	Public Health Importance	[67] *"I think, for the most part, women like to respond…The subject matter is one that women are willing to response to and share their story."* [68] *"We have discovered that participants are very eager and very willing to share their experiences or their story of their own individual pregnancies…So we have had very good feedback from the participants and very good responses to our survey."* [69] *"I think that if you were to talk to a sampled participant, I think that they would accept that this does seem like it is a benefit to myself, as well as other people among the maternal and infant health population."* [70] *"I think that when we detail the benefits of participating in the PRAMS survey, not just for that individual, but for the entire maternal and child health or infant health population, people are pretty willing to do so."* [71] *"From a perspective of people who are using the data is our experience, we have a lot of people who utilize our PRAMS data for various research projects, for community health assessments, for trends and monitoring of the health of the population."*

		[72] *"I do think it's a good source of data on things that aren't available on the birth record. We have used it to look at trends over time of important indicators for public health practice."*
Sensitivity	Willingness to Report Status	[73] *"My anecdotal evidence is that they are quite willing and often volunteer more information than what we asked."* [74] *"If they complete the survey, I think people like to share their experiences from their labor delivery."* [75] *"I think they are pretty willing. We know, in comparing it to the birth certificate, we see higher prevalence of some sensitive issues."* [76] *"We do get pretty consistent or higher reporting of smoking during pregnancy compared with the birth record, which makes me think that…you get good reporting…I think for other kinds of stigmatizing behavior or events that people might be less willing to report…we get pretty consistent numbers."* [77] *"I believe that some people are willing to answer the questions truthfully because the answer are anonymous…the way the data gets used, but I know there is some fear and stigma about answering correctly and truthfully."* [78] *"Overall, I think women feel comfortable answering the questions truthfully. But of course, we are not in the business of doing biometric testing to see whether they are being truthful or not. So that's the only caveat."* [79] *"I think the respondents are willing to report out accurately. I think there may be bias on mode, depending on how they answer the survey…But I think overall respondents are very willing to help out whether or not they had a positive outcome or negative outcome."* [80] *"The way we've structured our survey and education campaign and promotion, it's very much, share your story with us and share those experiences that you think as a new mom, other people can relate to. I feel like if it was a scale of one to five, how likely people are to be honest about their experiences, or willing to share, I would put them at a three or four."*
	Ability to Understand the Questions & Correctly Identify Status	[81] *"I think that the survey surveillance system does a very good job at testing and norming questions ahead of time. We are confident that by the time we are asking the questions of the participants, that the psychological and the user studies have ironed out any problems with the language…The big exception is language, of course, because we only offer the survey in two languages."* [82] *"The PRAMS questions are field tested prior to going out into the field. And so, they do their best to ensure that the questions are understandable. We don't hear a lot of feedback from women saying I don't understand this question."* [83] *"PRAMS has done a great job at doing their due diligence on the wording of questions to elicit the desired response and tweaking it as needed with feedback from states"*

		[84] *"I think participants understand the question. And I think there are great guides along the way."* [85] *"If moms have a question, they will call us or write it in the survey. Or particularly during interviews, if there are questions, then they might ask the interviewer for clarification, and we always debrief on that. There seems to be a very small amount of time when things aren't necessarily clear."* [86] *"I would say that this survey is pretty understandable to people. We partner here with our local university's survey center. And they have a positive view of the questions from a survey methodology point of view. And in my experience, there are very few questions where people ask for clarification, and usually are able to respond pretty quickly, which to me indicates that they understand the question and what it's asking for."* [87] *"I think the questions are very clear. And it uses language that people can understand. And I think that they're getting good answers."* [88] *"I think it does a good job. We're always instructed, even if we're developing our own state specific questions, or even at the CDC level, to try and keep it at a lower reading level so it will be understood by more women…They also give simple definitions that are added to the questions, to enhance the ability for the mom to really know what's happening, like gestational diabetes."* [89] *"The questions are written in an easy to understand format... a fifth to sixth grade reading level. So, I would say, the general population would be able to understand the questions."* [90] *"I think they survey has been constructed and designed carefully. Thinking about reading level and if there are any behavioral or clinical conditions."* [91] *"I think it varies by questions…I think some questions are very well written in plain language. For some questions that involve more medical terminology, there might be the need of the phone interviewer…to provide a follow-up explanation."* [92] *"The questionnaire itself explains in detail what the condition is, if it's referring to a specific condition, or it will give examples that the interviewer can use if the questionnaire is being done over the phone."* [93] *"We do have growing diverse communities…And so we're seeing issues with that, on the fact that maybe some individuals that we pull in our sample might not have English as their primary language or perhaps may not be able to read English very well. So, there's an issue with only having an English survey to distribute…It prevents people from participating if they wanted to."* [94] *"Our experience has been that most of the moms participating have a college degree, or some years of college or associate degree…We have to explain a lot to teens, some concepts in the survey…But I could say that most of the participants that are adults understand the questions."*

		[95] *"We have a team of people who review the proposed questions. And depending on what the questions are, we check with local experts as to whether they think that the targets of the survey, a mom, will understand and be able to respond to the survey in the way that we intend to collect the data."* [96] *"I think there may be some confusion with the way the survey is set up asking the questions before pregnancy, during pregnancy and after pregnancy."* [97] *"We find the survey is well organized in that the prior to pregnancy questions are at the beginning of the survey, during pregnancies middle and post pregnancies is at the end of the survey, but we do have to remind participants occasionally this is for this time versus now we're talking about this time period. So yes, clarification is required."*
	Validation of Data Collected	[98] *"We only validate certain items that we can link to the certificate of live birth because other than that, there's not a good way to actually validate a response from the participant."* [99] *"We make sure that the date of birth of the mom and the date of birth of the baby on the survey match what we have in our records. And if there's a discrepancy, we try to figure out if the birth certificate was an error…or if someone who put the data entry incorrectly misread her handwriting."* [100] *"Our mail is addressed to the mom and then they have to put in information to verify such as the date of birth. And same thing when we call the potential respondent, we ask them to verify some information and date of birth in hope of ensuring that we have the correct person."* [101] *"I would say that we do more in this area for the phone phase. So, we follow the protocol for confirming that we're talking with the correct person before talking about the survey, including name, birthdate, etc."* [102] *"In the introductory script that's a part of the protocol, the interviewer before starting the questionnaire by phone asks the person the name and date of birth and address."* [103] *"One of the first checks is that the date of the birth of the mother that came in from import and the date of birth of the baby, both match up on the survey to what we have from import. That's our first check that we have the correct mom, that she's actually the one who filled it out…And if we cannot with reasonable certainty, say that this is the mom that we are trying to get, then we don't accept that survey."* [104] *"Everyone should really be doing the mom and baby date of birth check. We do that regardless of the mode even though the phone interviewers are only asking when they consent."* [105] *"If it's within two years of the year we have on file, they will still go ahead and do the interview. And then the interviewer will let us know. And we will take a look at that…When we have data birth discrepancies that are beyond a certain amount…we always send those over to our Bureau of Vital*

		Records…They go back to their source, which is the maternal worksheet that gets filled up by the mother in the hospital, which then turns into birth certificate data." [106] *"We've actually gotten some really interesting surveys back sometimes where we found that the intended participant or recipient of the mail survey, gave it to someone else in their family that may have had a child recently and they would fill it out…But we found out that the birth date for the child and for the mother did not match up with what we had in PIDS. And so, we obviously couldn't accept that."* [107] *"I think that the way that we try to ensure that the intended participant completes the survey, well on the phone, it's easier because you're actually talking to someone but for mail, which is how we get most of our responses, we do certain checks, like verify the mom's birth date, verify the infant's birth date. And just ensure that you are talking to the right person as you're going through informed consent, you're verifying that you have the right person with the right name and right birth date."* [108] *"With mail, we're actually come across issues where family members will fill it out on their behalf…And we do accept those because it is up to the participant whether or not they would like to do that, but I think it's just a matter of verifying the correct information, the identifiable information for the participants in the survey."* [109] *"For the mail surveys, we just kind of have to take it as it is. If there are questions as to who completed the survey, we have staff in our area look at the survey and see if the responses fit together. Or if it seems like if questions are randomly answered. And then if there's an issue, we'll have a conversation about what to do with the data."* [110] *"This is not something that we've tried to do, just because I think we operate on the assumption that when we mail a survey, it is going to the intended audience, and our consent is targeted to the person filling out the survey to be the actual individual who the survey is addressed to. And I would say this is probably easier to ascertain over the phone because then you get their birthdate and their names and information that only a woman who's recently had a baby can be able to answer. So, on the paper survey, I wouldn't say that we have a good system for doing that. But on the phone survey, I'm pretty confident in our method of ascertaining who the person is."*
Positive Predictive Value (PPV)	Confirmation of Cases	[111] *"A few states have done some comparisons of what's reported in PRAMS, especially around smoking and other risk behaviors and what's also seen in other data sets. For quite a few studies, there's some areas where PRAMS does a great job, and then there's some where it doesn't."* [112] *"Birth files are always linked to our final weighted PRAMS data set. And so, the variables that would exist in both data sets can be confirmed and cross checked across both."*

		[113] *"Birth certificate is one that we have some crossover, but again, it has its own limitations based on how that data is collected, especially if it's collected in-person in the hospital. I think often we sometimes compare to other states to see potentially if we're getting similar data."* [114] *"Basically, medical charts that could be linked to mom's record…We also look at Medicaid when we're doing alternate contact sources. We look in the notes in Medicaid. We have direct access to WIC, we look in the notes and we can see things there too, that match up to responses on PRAMS. We're doing check and balances like that. So, we have a number of things at our disposal to be able to do that."* [115] *"Birth certificate data obviously is the absolute key. But again, we have used the hospital records for one study. And for that study, we consider hospital records the gold standard, but typically it's birth certificate data. And WIC, we've looked at WIC before too."* [116] *"We have national immunization data, we have WIC data, we have detailed birth certificate data…we look at all of those and connect them with the PRAMS data."* [117] *"PRAMS asked about breastfeeding and we will do other kinds of surveillance around breastfeeding. And look at combining and connecting those different modes of getting at the same topic."* [118] *"There's been a number of studies that look at PRAMS versus the birth certificate. There's been a couple where they add in the medical charts. And that's the closest you can get to actually double checking what they're saying on PRAMS. What is in the medical records is the gold standard because we're not doing face to face. We don't have the mom there. We can't take a test. We can't do a test for tobacco. We just don't have that ability. And all these different sources, they have their limitations. And you have to basically choose one and say, well this is the gold standard that we're going to try and measure off of."* [119] *"We have looked into that before. And we've done abstraction as the gold standard…We wanted to validate a subset of PRAMS data. We were looking at some of the outcomes…NICU admission for the baby, birth outcome, whether it was normal, low pre-term, maybe some behaviors during the pregnancy, prenatal care, smoking."* [120] *"In the past, we used to ask a series of questions about health conditions that were experienced by women and we worked to validate that with the hospital discharge data in our state to see how those correlated."* [121] *"I've either engage with more specific projects or specific investigations or use that data to perhaps develop a focus group or use that data to develop some sort of intervention or campaign or initiative, depending on the results of the information."*

		[122] *"This wouldn't be on an individual level…We do share the PRAMS data, an aggregate level with a lot of our partners and many of them confirm patterns that we see in the data…When we share our findings with community health workers, doulas and other partners, they confirmed that what we're seeing in PRAMS is what they are seeing in practice. But on the individual level, we don't do any validation of those numbers."* [123] *"Since that information is aggregated, I don't know of a way that we would be able to identify a false report other than if it was compared to, add the identifying demographic for an individual report and compare to the correlating birth report, but I am not aware of that being the case."* [124] *"Doing focus groups, using some of the topics that come out of PRAMS to develop qualitative questions and our focus groups. I would also say in terms of other data sources, the BRFSS data. And then also thinking about like America's Health ranking data, and some of the Healthy People information, all of the data collected from the National Center for Health Statistics. So, it just depends on what the topic is."* [125] *"I think PRAMS is always a good place to start. But of course, we confirm it with either state data, looking at state vital records data and looking at morbidity and mortality data across the state…So depending on the topic, we have data sources that we can use to sort of confirm what the PRAMS data is. Or we do some primary data collection through focus groups or other means."* [126] *"We have not necessarily carried out any investigations. A good way to do that would be accessing medical records. Or I guess doing actual interviews and that I think would require a lot more work and funding to verify."* [127] *"Nothing that has come out of our office. There are researchers and graduate students at various universities who are assigned to the task of doing that."* [128] *"I'm not aware of any other than access to prenatal care, but other behaviors, I don't have a way for us to validate those."*
	Prevalence of Health-Related Events	[129] *"For the most part, PRAMS is one of the major data sources that talks about what are the barriers to women in entering care early. So, we've been able to use PRAMS data to sort of look into those barriers more specifically, or design interventions around those barriers. I would also say the same thing for postpartum care."*
Representative-ness	Generalizability	[130] *"I think that its main strength. It really collects bellwether information on what's happening throughout the country, but also regionally, and then down to other divisions (i.e. county, region, city). And it seems to have done so well over the years."* [131] *"Since our sample is small, we are able to look at the state overall over time, but we can only look at counties that are a little bit larger in population. For a lot of our more rural counties, we don't necessarily have enough data to really make meaningful decisions and to be able to feel confident that there are*

		significant differences unless we aggregate a lot of years. And that can also come with some issues of its own when there's different trends or policy changes over time." [132] *"Within our state, it's not possible to look at geographic distribution of attributes or health events, as much as our partners would like who always want county data, but that's not what we're designed to do."* [133] *"For the majority, PRAMS is able to monitor trends in generalizable ways. I will say that the limitation is that it's not designed to go down to some sub-levels. And so, as long as you understand some of the limitations of what you can and can't do with the data, then I think it is serving its purpose."* [134] *"I think the increased response rate really helps…In thinking about the population, our sub-populations are getting closer to the required 55% response rate threshold to release their data. And thinking about how those groups are kind of dispersed geographically in the state, its more and more appropriate to generalize PRAMS data to some population across the state."* [135] *"I do think that its generalizable for 95% of our birth population. It's not generalizable for women who identify as something other than White, non-Hispanic. And that's a huge issue…For some of our participants, it is very generalizable but for others, sadly it is not."* [136] *"I think it does a very good job at telling the story of state data for any state who has a PRAMS program…This is a trend. And it's an accurate trend of what is generalizable to the population in that state."* [137] *"I agree with that we're able to look at the data between states and nationally. But I disagree because the survey questions can change between the different phases…So it's hard to keep track of it from year to year if the question has changed or is asked in a different way. It's hard for us to compare it between year to year and see if there is a trend."*
	Population of Interest	[138] *"The sample comes from the demographic registry birth files and is representative of moms that give birth to a live baby during the period of study. All births are registered. Every mom needs to register the baby to have a social security number and other benefits. And babies are mainly born in hospitals. So, I can say that 100% of babies born are registered."*
	Error and Biases	[139] *"With the weighting process of the sample data, it takes into account the factors related to bias and non-coverage. So, the data that is collected can be generalized to the entire state's population."* [140] *"There are some limitations just because it is a self-report. And it's just a representative sampling."*
Timeliness	Surveillance System Time Intervals	[141] *"Of course, we wish we had it earlier and more timely, but if you know the cycle and just plan accordingly for that cycle and that process is consistent, its workable."*

		[142] *"So, it's something we've accepted, we try to mitigate it by being as fast as we can to get data organized and ready to go."* [143] *"Sometimes we have to wait for straggler batches and that can delay us sending the file to CDC. So, I think one year is reasonable."* [144] *"My goal as the project coordinator is to get all of the information, all of the data set, the batches, the birth file, everything ready to go as soon as possible so that we can get the data back as quickly as we can."* [145] *"I am not sure how else CDC could do it. If they can continue this trend of having to be under six months from the end of data collection, that'll be a huge help…When its lasted more than a year, that's not acceptable."* [146] *"I definitely think that the faster we get the data, the better. I will note that the timeliness of receipt of our data has gotten better. Over the years, it used to be longer than that, and they really worked to shorten that timeframe. The faster we can get it, the better in term of utilization of more timely data…But knowing the process that has to take place to get the data, we understand how that timeframe works."* [147] *"CDC has really worked hard on their timeliness as far as getting the weighted data back to the states…Final data aren't collected…until June. So, I'd say that we've gotten the timeline closer to six months rather than a year."* [148] *"To be one year behind for analysis, I think it is very good. That's very timely. And it's something that they've really done a much better job at getting us back to that. It is timely…it hadn't been in the past."* [149] *"I get the protocol and the timing of the sampling. And I get that you need a full calendar year because there is some seasonal variation…I get that data collection does extend into the next calendar year."* [150] *"CDC has done a much better job most notably in this past year about getting our weighted data back much quicker. In prior years, we used to wait up to two years at least to get our data. The main thing though is because we've doing surveillance on the year of birth, we are getting births that can be through December. Then the PRAMS protocol is that they're followed up for three months. And so, we can't even close out our batches on the last birth of the year until at least March or April just for follow-up purposes. Then you want to give at least a few months for the closeout activities and the weighting process."* [151] *"I think this is probably the biggest complaint people have about PRAMS…and certainly things are better now… This year is the exception where they really pushed to have everything in by June 30th. And then six months later, they're able to provide the data set. So, I would say this is a great direction."* [152] *"So, I think one of the major moments of pride for the PRAMS program is that it is very good at getting its data ready and submitting its birth file and getting data back in a timely way. So, I think that we've come a long way over*

		the last few years…I feel like we are getting our data pretty close to the year when it was collected." [153] *"Historically speaking, the sooner you get your annual birth file in and the sooner you submit your batch files, and get all your batches expired and verified, the quicker you can get your data processed and weighted by the main CDC. That's of course if you've met your response rate goal, right now that's 55%. That wasn't the case this year. We got it in pretty early, but unfortunately, they decided to do a different kind of ranking for states to get their data processed…And so we weren't as high up on the list as we wanted to be, but that's okay…Most people here are pretty understandable when it comes to that kind of stuff."* [154] *"In order to include the full calendar year in the analysis, it's going to be a year behind from when the information was actually collected. It's not ideal as what you would like for prevention efforts because what was a problem a year ago might not be the problem at this particular moment in time; however, it's the best that we have to go from. So overall, I think it is timely."* [155] *"I think we would all love to have more timely data. But it's a balance between collecting valid representative data and then weighing it with getting data in more real time that may not be as valid and reliable. I do think PRAMS a few years ago was really, really slow in turning the data and have since improved…I do think that they are taking efforts to improve the turnaround for sites that are participating."*
	Identification of Trends and Intervention Effectiveness	[156] *"Yes, pretty timely. We are not dealing with infectious diseases and one year is enough time to see changes in behaviors."* [157] *"Most indicators don't change that much from year to year. And so, we don't often need to do that really quickly due to changes in the population. But I will say that this year is probably an outlier because we know that the needs and experiences of maternal and child health populations have been really disrupted this year. And obviously, we don't have any PRAMS data right now to inform our response to either the Covid pandemic or how the pandemic has affected families."* [158] *"It's a bit harder to add questions that are of timeliness and current issues."* [159] *"It really is not timely, at least in terms of like emerging issues…if we're going to have to wait a year to get responses, I feel like Covid will be a very different conversation that what it is now. For some things, I think it's pretty reliable for like chronic diseases and some of the measures that remain consistent year to year, but for emerging issues…PRAMS fails the test."* [160] *"I think that the data should come faster. Programs are awarded per year and activities are decided upon in that timeframe."* [161] *"It's the biggest complaint we get from people…We wish that we could have more up-to-date information. Part of the problem is it's a yearly surveillance*

		system. If it were an every quarter surveillance system, or every half a year, maybe that would be better because we'd be able to get more timely data." [162] *"I understand why it takes that amount of time, but many of our partners are gathering local and regional level data within the states and using that data to direct their programming in a much more timely manner. And it takes us so much longer at the state level to receive that statewide level data on the same indicators…It's very frustrating to them in trying to determine whether we have a role to play in their efforts."* [163] *"That's frustrating for us from the standpoint of by the time we get the information, many times a true public health prevention is not possible because to practice true preventions, you don't find out that there is a trend and a possible issue until you're already traveling down the stream so to speak. So, it is not optimal. I understand why there is the time, but it definitely does create some barriers."* [164] *"And so local partners often mentioned that it would be much more helpful to have faster data, especially thinking about emerging issues like Covid-19. If we would have been able to develop specific questions and then ask either a proportion of our sample or ask questions very quickly after the pandemic began about the impact, that would give use much more actional data. So, there are barriers to utility of PRAMS data when it comes to public programmatic adjustments."* [165] *"So, at the state level, this is seen as timely data. But our local partners often struggle to use the data in a meaningful way. Because if they identify an area of interest in the data that's already a year old, then they implement a program to address it, they have to wait even longer, a year from the time that the program is implemented, to see if there's been any change. Being state data makes it hard to see direct programmatic impacts unless it's a state-wide program or a specific population that is geographically clustered."* [166] *"I know there is a lag in data. One year actually is not that bad on the whole scale of things. But for me, one of the things that concerns me is if there's a lag between years either because there weren't enough people who took the survey or there were issues analyzing it…Not having data for three years was a little bit concerning. But the one-year lag is not ideal but it's not the worst."*
Stability	System Longevity & Utilization	[167] *"It does allow us to do what we can do to collect PRAMS data and keep it going."* [168] *"I think its operational and functioning as it needs to."* [169] *"We were told that if we wanted to start 2020 data collection, that we would have to submit a contingency plan…show that you are able to still conduct your operations, still have access to PIDS and mailing and other things if remote…We were able to start in the same month, and that didn't affect us significantly…Even in a crazy year such as 2020, PRAMS have not had to cease operations at all."*

		[170] *"There are often times where we have to do a workaround or work with IT because a certain capability isn't working ideally. And so, there are sometimes when we have to adjust how we do something like create a mailing or log a survey."* [171] *"I would say 99.9% of the time, its fully operational."* [172] *"90-95% of the time PIDS is running fine. And in that time when its not, the benefit of having a phone calling team that is in-house as opposed to many other PRAMS states that contract out their phones is that our phone staff is part of our operations staff. So, if they can't make phone calls, we can prepare mailers, send out gift cards or do any number of other tasks that go along with managing programs such as PRAMS."*
	Dedicated Resources	[173] *"We get a decent amount of funding from CDC PRAMS, but we also have to ask for additional support from our different programs that use PRAMS and support questions on PRAMS in order to do things to increase the response rate, such as providing gift cards."* [174] *"Right now, we are able to collect decent funding to have a decent sample size and meet the required CDC threshold and response rate. Of course, we'd all love to have a larger sample size, which would require probably a little more staff time in addition to funding."* [175] *"The funding that's provided by CDC to run PRAMS is not enough. I think the intention is that states will also invest in their own surveillance system, which is reasonable. But in a state like mine, where the state public health infrastructure is very underfunded, there just isn't a lot of extra resources. And often our leadership would prefer to invest in programs rather than data collection."* [176] *"If PRAMS was just relying on CDC for funding to sustain the program, it would not happen. I think currently, they only provide us with about half of the budget. And so, we do have to fundraise. I would say that our program would probably not exist if we just relied on CDC."* [177] *"As far as funding and resources are concerned, we are supported by the CDC PRAMS grant, and jointly by Title V. The bulk of costs with a program such as PRAMS goes toward staff time…Another large cost is provision of gift cards to participants. And do I would say that most recently through other supplemental funding…we have had sufficient resources."* [178] *"There aren't really resources available to offer the kinds of incentives and rewards to participants to get really good consistent response rates. This year, we were able to implement a $5 pre-incentive and a $20 cash reward to participants. But that was because we got some extra funding. It's not something that we can sustain with the amount of funding that we have...With the current funding level, we're really not able to get the best sample sizes or response rates that would really ensure reliable and available data."* [179] *"With [CDC] new prioritization criteria, our state is in the latter half of states to be weighted, even through we gave them out birth file six months ago.*

		So, I don't know if it's a staff issue, if they just don't have enough statisticians to do the weighing in a more timely fashion. But that's another area where I feel like there's room for improving the availability of the data." [180] *"We have nobody that we can call if our phone interviewers are working on the weekend…There's no support line. We have to wait until the weekday. The resources are not there to be completely comprehensive. I think [CDC] is strapped for resources and there definitely room for improvement. Should we ever have funding to be able to add to the team and do more, that could be useful to states in these off hours. That's where we're kind of lacking."* [181] *"We want there to be someone available for PIDS support outside of the eight to five office hours. There will be an issue where something crashes with PIDS or does work on the weekend. But there isn't anyone to fix it, necessarily on the weekends…sometimes it impacts it so that we can't call again or can't access the system until Monday morning. And so that's a barrier to putting data into the system and calling moms."* [182] *"PRAMS has the Support Now system. It's like personnel that provides assistance with any situations related to the PRAMS integrated data collection system. We sent a note by computer and they quickly respond to any issues we have with the system."* [183] *"CDC has their own full-time dedicated IT staff and programmers to deal with any updates to the system programming, adding in the new surveys when the survey cycle changes and then also troubleshooting any issues that arise."* [184] *"I think that [CDC] could probably use more support with the data weighing. And in terms of the sheer volume of it at the CDC, I think that is they had more resources, that they could maybe hire more people to help with that process. It might help with the timeliness of receipt of the weighed data."* [185] *"We're a pretty small project. We get most of our funding from the U.S. CDC through our PRAMS grant, but we also get state funding…we do have the resources to help the data become available and reliable. Of course, more money is awesome. You can do more things and can translate surveys and you can conduct more outreach to specific populations. And you can just broaden your reach with the survey and hope to broaden your participation."* [186] *"Even in your mailing in-house, and you don't have enough resources, enough staff to stay on top of things, PRAMS doesn't stop. Its constant and you've got several batches open at once."* [187] *"If you're not paying close enough detail and have a good idea of where all your batches are to stick to the timing and stick to the process to optimize response rates and keep track of administrative things, that can lead to failures and that can lead to shutdowns…Need competent staff and resources."* [188] *"All PRAMS operations are in-house…which really allows kind of hands-on management from the program leadership. We have the staff working in our*

		office. And we have phones and can quickly respond, which I think might be a little bit different if you contract out for those services." [189] *"We looked at whether we wanted to keep the services in-house, or we wanted to contract out, and for us contracting out was almost cost prohibitive. And we decided to keep services in-house. And we worked on a lot of different efficiencies. There's a lot of working side by side with the team where you can stay on top of these things that may otherwise interrupt a program."* [190] *"We have a contractor that handles all operations."* [191] *"We have a phone vendor, who's doing surveys for us. So that's off-site, but we do our mailing in-house."*
	Scheduled & Unscheduled Downtime	[192] *"The main data collection system, PIDS, has been down from time to time for like routine maintenance or upgrades or to fix issues. But usually when it goes down, it is only down for one to two hours. Usually no more than half a day and its back up and running."* [193] *"We have both scheduled and unscheduled downtimes and usually it is resolved within a 24-hour period."* [194] *"When it comes to the reliability and availability of a surveillance system, we never have huge chunks of time when PRAMS is out of commission or out of order. We're constantly collecting the data."* [195] *"Never any severe downtimes where it would affect the operations of our project."* [196] *"There have been a couple of instances…parts of the system have had hiccups, interruptions, but I think the team has updated protocols to kind of harden against some of those."* [197] *"PIDS software is solid…and no software is without its glitches. There have been some outages…They've had to do a bit of maintenance to the system itself…The CDC does attempt to notify us with as much advance notice as possible."* [198] *"Sometimes they need to resolve or fix situations. And they inform ahead of time…But we can continue with the interviews by paper. And that doesn't affect the data collection, at least by phone. And the other way is by mail, so the mail continues to be received in the office. So, it doesn't affect us at all."* [199] *"We had a little downtime this year, with the beginning of the Covid pandemic, where we had a one month delay as we transitioned to working from home…But the last time I can remember even a scheduled downtime was years ago when they were upgrading our data collection system. So, for the most part, PRAMS runs very smoothly and on time and with very, very limited downtime in the process."*

		[200] *"The CDC PRAMS team and technology team has been extremely responsive and had very clear communication about when things will be down and when they will be up…It certainly has not affected our data collection."* [201] *"Unscheduled downtimes, not in terms of the overall surveillance system, only in term of PIDS…It has been annoying, but I don't feel that it has jeopardized the collection of data. It's more programmatic annoyance than it is a problem of the reliability or validity of the data."* [202] *"Occasionally, we have some downtime with our PIDS system…And that is sort of random sometimes, but usually very limited…So I guess the Covid might be considered an unscheduled downtime, because it was not expected."*

Source: Author's calculation

Appendix 23: Simplicity Key Themes, Detailed

(1) Program Structure

PRAMS operates through an interorganizational collaboration that is critical for effective implementation. The success of PRAMS is largely attributed to the partnership between CDC and state health departments. Within the health departments, PRAMS program structure involves several existing organizational units, including Maternal and Child Health and Vital Statistics[39]. The CDC provides ongoing support of the PRAMS program, including protocols and procedures, recommendations, documentation, software, and available staff to troubleshoot upon request [30 48 52]. Most PRAMS program activities are conducted by the states, usually by health department staff members (i.e. project coordinator, data manager, etc.)[46]. Each state has a director that is responsible for program oversight[46].

Each participating site has a PRAMS Steering Committee comprised of participating health department representatives and individuals from the broader public and private community[46 55]. The Steering Committee is established to provide oversight and guidance for the program, including advising PRAMS staff in the development and selection of state-specific questions and on the use, dissemination, application of findings[13 27]. The committee may use PRAMS findings to guide recommendations for developing or modifying intervention programs or for securing resources for program changes[46]. The PRAMS Steering Committee meets at least once a year and may meet more during the initial development and start-up of PRAMS, questionnaire revisions, and when data analysis begins[46].

(2) Staff Training Requirements

CDC requires training for staff members involved in any aspect of PRAMS question development, data collection, and analysis. Necessary training materials and documentation for staff training are provided by and arranged for by CDC[46]. Training materials for the development and testing of state-developed questions include topics such as assessment of the quality of individual questions

and cognitive interviewing techniques[46]. Telephone interviewer training is required for the data manager and all telephone interviewers and refresher trainings are conducted at least once per year to review changes to data collection activities[46]. Human subject training is required to ensure that all PRAMS staff is knowledgeable about human subject protections and understand the implications of breaches in protocol[46]. Refresher trainings are conducted annually, and all modules are repeated in the case of a breach in protocol[46]. Future staff members hired to work with PRAMS states are trained by the project coordinator[46]. In addition to interviewer training and human subject training, relevant staff will need to receive training on the use of the PRAMS Integrated Data Collection System (PIDS) and Software for Survey Data Analysis (SUDAAN)[46]. CDC may arrange additional staff training upon special request[48].

(3) Start-Up Activities

PRAMS is an ongoing U.S. state- and population-based surveillance system that was established in 1987 as part of an Infant Health Initiative when congressional funding was provided to CDC to establish state-based programs[38]. In the mid to late 90s, the demand for PRAMS was high and the CDC was awarded additional funding to expand the program into new states and continue funding existing states[44]. As states receive funding, they are required to adhere to the research protocol developed by the CDC to establish their PRAMS program. The protocol is the cornerstone of the state PRAMS operations, assuring the standardization, consistency and continuity of the program[44]. It is based on the most current research and provides valuable historical information about the program development and design. The protocol is to be tailored to each state and includes the following 7 components: Personnel, Training, and Steering Committee; Sampling; Data Collection; Data Management; Analysis, Use, and Limitations of Data; Human Subjects Protection; and Evaluation[44].

With the availability of the model protocol, it is anticipated that the timeframe from initial funding to data collection will take approximately 10-14 months[52]. During Months 1-4, the CDC model protocol is reviewed carefully, the Steering Committee is organized, staff members are hired (if needed), topics are selected for the state analysis plan and state-specific portion of the questionnaire based on priority areas, and sampling scheme and sample size estimates are developed[52]. During Months 5-8, states submit their draft state protocols, state-specific questions, and sampling programs to the CDC for review[52]. Revisions are made based on CDC feedback and final documents are submitted to CDC by the state[52]. Additionally, the final questionnaire and state protocol are submitted to the local IRB[52]. States must ensure that their local IRB has a Federal-wide Assurance (FWA) number that is current and not expired[52]. During Months 10-14, IRB approval is secured, CDC conducts an installation/training site-visit, all project equipment is acquired, questionnaires are printed and data collection begins[52].

(4) Data Collection & Management

All participating PRAMS states are responsible for data collection activities and are required to follow the standardized data collection protocol developed by the CDC. PRAMS is a mixed-mode (mail and telephone) surveillance system and is based on Dillman and colleagues' tailored design method that incorporates techniques developed to enhance survey responses[30]. These techniques include personalized mailing packages, use of responses incentives and rewards, and repeated but varied contact attempts[30]. Because of the advantages of mail surveillance, particularly cost and access to mailing addresses, this mode is used as the primary form of data collection[48].

PRAMS relies on state's birth certificate files to select a defined sample of women who have recently delivered live-born infants[3 30]. Most states use health department staff to conduct mail survey operations[30]. However, recently, there has been an increase in the number of states contracting out data collection activities[30]. In 2016, 12% of states contracted out all data collection activities, 51% contracted out telephone follow-up activities only, and the remaining 37% conducted all activities at the health department[30].

PRAMS data collection and management require ongoing, daily activities by support staff. Each participating state draws a stratified, systematic sample of 100 to 250 mothers every month from eligible birth certificates[3]. Eligibility requirements included all residents who delivered a live-born infant in a specified interval of time[55]. Each month, numerous and varied contacts are made in an effort to encourage sampled mothers to complete the PRAMS questionnaire[3]. The first contact is a mailed pre-letter that introduces PRAMS to the mother and informs her that a questionnaire will soon arrive[3]. Within seven days of the pre-letter, the initial questionnaire packet is mailed and includes the survey, informed consent page, calendar and resource brochure[3]. Seven to ten days after the initial questionnaire packet, a tickler is sent to serve as a thank you and reminder note[3]. Mothers who do not respond to the tickler within seven to fourteen days are mailed a second questionnaire packet[3]. A third questionnaire packet is mailed to all remaining non-respondents seven to fourteen days after the second questionnaire[3]. Telephone follow-up is initiated for all mail non-respondents seven to fourteen days after mailing the third questionnaire[3]. This sequence of contacts is attempted for each monthly sample of mothers[3].

While mailing addresses are available from the birth certificate, the same is not true for telephone numbers to contact mail non-respondents[48]. PRAMS staff conduct a comprehensive search for telephone numbers for women who did not respond during the mail phase[48]. These sources include, but are not limited to: Medicaid, WIC, or other state-maintained databases, directory assistance, internet databases, motor vehicle registration records, and voter registration or other local government records[48]. For telephone follow-ups, fifteen call attempts are made to each viable telephone number[48]. To increase the likelihood of reaching a mother, calls are staggered over different times of the day (morning, afternoon, evening) and different days of the week (Sunday-Saturday)[48]. Telephone follow-up for mail non-respondents add substantially to the number of completed questionnaires states are able to obtain[48]. Aggregate data from 38 PRAMS states for

2011 show that telephone follow-up increased the overall response rate by an average for 14%, which a range of 3% to 22%[48]. The combination of multiple contacts and mixed data collection modes has proven effective in increase response rates while minimizing costs in PRAMS participating states[48].

PRAMS Integrated Data Collection System (PIDS) is the primary data collection instrument required for conducting daily PRAMS operations. PIDS is a secure, web-based system developed by CDC to assist in scheduling and tracking data collection activities, recording data from mail and telephone questionnaires, and generating reports to facilitate daily operations[3]. States import contact information from the birth certificates into PIDS and samples are processed in monthly batches to balance the workload throughout the year[30]. After a state completes data collection, cleaning, editing, entry verification and monitoring of a batch, the information in PIDS is extracted, allowing states to make the data available to CDC for further data processing weighting[30].

(5) Data Analysis

States are responsible for analyzing their PRAMS data to monitor the health of mothers before, during, and shortly after pregnancy within the state. Before analyses of PRAMS data can begin, several preparatory activities must take place, including developing an analysis plan, training staff involved in the analyses of PRAMS data, and preparing the PRAMS' master analysis data set[50]. A state's analysis plan is used as the guide for planning and conducting analyses of PRAMS data and takes into account the state's prioritized data needs[50]. All staff members involved in PRAMS data analysis are trained for analysis of complex survey data[50]. Master data sets are evaluated for potential concerns for analysis, including groups with low responses rates, questions with high rates of missing data, or other issues that may impact the analysis[50].

At least three analytic designs may be used in the analysis of PRAMS data, including descriptive, inferential/analytic, and methodologic[50]. Descriptive studies describe a health problem or behavior in a state and include the prevalence of a problem, trends over time, and characteristics of women who experience the problem or behavior[50]. Inferential or analytic studies investigate relationships between behaviors or health outcomes in order to make inferences about possible causes or contributing factors to health problems[50]. Methodologic studies assess and evaluate the PRAMS data collection methodology to determine how to improve it, such as increasing response rates[50].

PRAMS not only provides state-specific data, but also allows comparisons among participating states because the same data collection methods are used in all states[26]. The CDC is responsible for comparisons of data between states, as well as descriptive and analytic studies of selected topics using data aggregated across multiple states[50]. Variations across states may be attributed to population differences in sociodemographic characteristics, differences in state and local policies, and variations in the availability of and access to health-care services[41]. These state comparisons

can help maternal and child health organizations across the country improve their programs and policies.

(6) Level of Integration with Other Data Sources

Birth certificate files serve as the sample frame for identifying eligible PRAMS mothers and are the most common data source linked with PRAMS[30 36 38 39]. The linkage provides added value to PRAMS by facilitating stratification and weighting of the PRAMS data to reflect the total birth population[15 40]. Selected maternal and infant characteristics are extracted from birth certificates and linked with mothers' responses on the PRAMS questionnaires for analysis[3]. Many states have linked PRAMS data to other data sources include death certificate data, Medicaid records, office of corrections records, child protective service records, various health department records, and follow-up studies[30 31].

Appendix 24: Flexibility Key Themes, Detailed

(1) System Tailored Design & Methodology

PRAMS is funded and administrated by the Centers for Disease Control and Prevention's Division of Reproductive Health in collaboration with state health departments[25]. It is designed to monitor selected self-reported maternal behaviors, conditions and experiences that occur shortly before, during and after pregnancy among women who deliver live-born infants in participating U.S. states and territories[38]. The CDC allows states the opportunity to tailor aspects of the surveillance system, such as scheduling of mailings, survey topics and priorities, state-specific branding and appearance, stratification plans, priority population groups for oversampling, and use of response incentives and rewards to meet the state's unique needs and populations[30 32]. The Dillman's Tailored Design Method adopted by PRAMS recognizes that individual states may need to modify components of the data collection methodology, including personalized mailing package, incentive tokens, and repeated but varied contact attempts, to ensure maximum response rates[48].

Over the course of the PRAMS project, there have been several examples of the use of alternative methodologies in an effort to increase response rates[48]. A hospital-based methodology was used in the early 1990 but was abandoned due to cost and lack of ability to collect data in the early postpartum period[48]. In 2001, Colorado PRAMS was awarded funding to intensify community engagement and outreach to the African American community by providing targeted higher value rewards[48]. In 2006, the Yankton Sioux Tribe of South Dakota was awarded funding to employ intensified community outreach, targeted higher value rewards, a WIC clinic survey delivery component, and a residential hand delivery component to address the challenges of reaching American Indian women in the rural communities[48].

The survey methodology emphasizes the importance of using the appropriate questionnaire format for the mode in which the respondent will complete the questionnaire[48]. For the self-administered mail questionnaire, it is designed so that the respondent can read and fill out the questionnaire

without the presence of an interviewer[48]. The interviewer-administered telephone questionnaire contains the same questions as the mail questionnaire; however, the questions are reformatted as necessary for oral administration[48]. For example, interviewer-administered telephone questionnaire includes prompts and instructions for the interviewer that are not read aloud to the respondent[48]. Although each questionnaire format has variations, the PRAMS project ensures that all questions and instructions are uniformly and consistent with one another[48].

CDC supports English and Spanish versions of the survey and other documents[30]. Additionally, New York City uses a Mandarin version of the survey that the city developed and supports independently[30]. Questionnaire formatting and appearance are the same in all languages[48]. Future methodological efforts will focus on maintaining acceptable response rates overall and further improving response rates among higher-risk groups[31]. For example, some states are already exploring using different incentives for different subpopulations, offering substantial cash rewards ($20 or more) to women in high-risk subpopulations, developing culturally sensitive survey materials, and using other avenues (media, faith-based groups) for publicizing PRAMS to improve response in high-risk populations[31].

(2) Technology

When it comes to incorporating the use of technology into its modality, PRAMS has been a slow adaptor. For several years, PRAMS has been in the process of piloting a web-based version of the questionnaire[48]. However, a web-based survey was never rolled out to participating sites. Many sites are demanding the adoption of a web-based survey for ease, accessibility and availability. It is anticipated that an online survey will alleviate burden for respondents to return mailed surveys and make it is easier for respondents to complete the survey using their personal cell phones or computers. Additionally, it would alleviate the burden of staff preparing hundreds of mailers each month, doing data entry once mailed surveys are received, and conducting telephone interviews. Transitioning to an electronic and paperless survey would allow PRAMS to take advantage of new technology, potentially increasing the overall flexibility of the program.

(3) Questionnaire Customization

Each state's questionnaire consists of three types of questions: (1) core questions common to all PRAMS states, (2) standard questions developed by CDC and made available for selection to all states, and (3) state-developed questions[30]. The core questions are standardized questions that appear on all states' survey, which allow for multi-state analyses[17]. These standardized questions generally account for 55% to 60% of the questionnaire and include topics such as preconception health and care, prenatal care (content and timing), perinatal substance use (alcohol and tobacco), contraception, breastfeeding and infant health[30 48].

In designing their surveys, states can choose from a pretested list of standard questions developed by CDC or develop their own questions to address state priority topics and data needs[5]. Standard questions on topics not covered in the core set, as well as all state-developed questions, are placed

in a separate section at the end of the survey[48]. When appropriate, standard questions that relate to core topics can be inserted among core questions, resulting in a unique survey for each state[30 48]. Standard question can provide comparisons among states that select the same standard questions in their surveys and include topics such as assisted reproductive technology, social support and services, injury prevention, physical activity, and oral health[27 48]. States have the opportunity to supplement the standard questions they select with questions that address additional priorities of importance to their individual state[48]. State-developed questions are designed and pretested by the state and incorporated into the state-specific portion of the questionnaire[48]. The unique customization of the PRAMS questionnaire allows the ability to provide state-based estimates, in particular on state priorities for which data is needed to implement relevant programs and policies, as well as monitor state-specific performance measures[33].

In some states, child abuse reporting laws may apply to the PRAMS project staff[39]. These states have two options available to deal with the collection of abuse information on the survey. First, states can choose to omit the abuse questions from the surveys sent to minors[39]. This avoids the reporting issue by not asking minors questions about physical abuse[53]. Second, states may decide to ask minors about abuse and will include a statement in the informed consent letter that informs minors about reporting requirements[53]. Consequently, different questionnaires may be available for adults and minors[48].

(4) PRAMS Questionnaire Revision

The PRAMS questionnaire is revised periodically, approximately every three to five years[8 27]. Throughout the life of the project, PRAMS has been revised seven times following its debut in 1988, which is referred to as Phase 1[44]. With each revision or new phase of the questionnaire, adjustments are made based on emerging issues and changing priorities[30]. These adjustments include modifying or removing existing questions, adding new questions, reducing the number of core questions, prioritizing core questions and the selection of standard questions, and changing the questionnaire to a two-column format[33 44].

The PRAMS questionnaire revision process typically begins two years before a new questionnaire is placed in the field[30]. First, an evaluation of the current questions is conducted to identify questions that should be modified or removed[30]. Questions are evaluated for item nonresponse, write-in responses, and whether respondents correctly followed skip patterns[41]. CDC also solicits requests for new topics and enhanced questions on existing topics[30]. Then, new and modified questions are sent to CDC's National Center for Health Statistics Questionnaire Design Research Laboratory for cognitive testing[30]. Once questions are revised based on cognitive testing feedback, the questions undergo field testing to evaluate the wording and flow of the survey before the questions are finalized[30]. Currently, the PRAMS questionnaire is in its eighth revision[30].

(5) Supplements

PRAMS has proven to be a versatile surveillance system through its use of questionnaire supplements. PRAMS supplements are short lists of up to 12 questions on an emerging topic that are quickly implemented across some or all participating states[30]. Supplements are able to leverage the existing state-based PRAMS infrastructure, allowing timely data for analysis and dissemination[30]. In between PRAMS Phases, questionnaire supplements may be developed to append to the end of the regular survey and are used for a short period of time for rapid data collection[5]. Results from the supplemental data collection are used to inform programs and policies at the state and national levels, facilitate partnerships, and demonstrate the timeliness and utility of PRAMS data.

To date, supplements have been developed for a variety of topics including family history of cancer, Zika virus, marijuana and prescription drug use, disaster preparedness, and coronavirus[30]. In 2009, CDC PRAMS received funding from the CDC Immunization program to collect data on H1N1 and seasonal influenza vaccines among pregnant women during the 2009 and 2010 flu season[44]. In 2016, the PRAMS implemented the Zika Supplement to support ongoing Zika awareness, prevention and surveillance in U.S. states and Puerto Rico[6]. In 2017, six PRAMS states implemented a survey supplement on marijuana and prescription drug use[44]. Because of their success in addressing emerging issues, supplements have become a standard part of the PRAMS methodology. More recently in 2020, CDC implemented the COVID-19 Supplement to collect data on the effect of coronavirus on pregnant and postpartum women and infants[5]. Findings from the COVID-19 supplement will inform federal, state, local, tribal and territorial public health response activities to support mothers and infants during the pandemic.

(6) Partnerships

PRAMS has partnered with external organizations to evaluate programs serving women during and after pregnancy[30]. An example is the partnership between PRAMS and the W.K. Kellogg Foundation. The goal of this partnership was to use PRAMS data to assess the potential impact of the Kellogg Foundation's interventions of improving maternal and child health outcomes[30]. In 2019, participating PRAMS states modified their samples to oversample Kellogg Foundation target communities in their states, including minority and low-income groups[34]. In the regions of the state where Kellogg Foundation programs were initiated, additional survey questions were added and surveillance methods were enhanced to ensure adequate participation and representation of the population of interest[34]. Throughout this partnership, PRAMS oversaw the implementation of sampling design and development of the questions to meet the data needs of the Kellogg Foundation[34]. Both PRAMS and the Kellogg Foundation had a collective interest of promoting health pregnancies, healthy birth weight, and optimal feeding for the growth and well-being of infants[34]. This collaboration with the Kellogg Foundation was the first partnership between PRAMS and a private foundation[34].

PRAMS collaborated with the Maternal and Child Health Bureau (MCHB) in the Health Resources and Services Administration (HRSA) to evaluate the Healthy Start Program[44]. Eleven participating states were oversampling Healthy Start clients who gave birth in 2017 and 2018[30]. The data was used to compare Healthy Start participants with similar populations not participating in Healthy Start[44].

The aforementioned collaborations have prompted participating PRAMS states to expand their partnerships to other state departments (i.e. mental health and school health) and outside community-based organizations to better guide MCH programs and services[34]. Partnership building allows PRAMS the opportunity for surveillance enhancements, such as improving its questionnaire flexibility and adapting new sampling methods for meeting their partner's objectives[34]. It has also equipped the PRAMS project to effectively measure and evaluate new programs and systems and to expand its sampling frame to capture hard-to-reach populations[34].

Appendix 25: Data Quality Key Themes, Detailed

(1) Quality Control

PRAMS incorporates a number of quality control measures. First, pretesting all PRAMS questions before they are placed on the questionnaire uncovers potential problems that may not have been anticipated[48]. CDC conducts two types of pretesting on newly developed or revised questions: cognitive interviewing and field testing[48]. Cognitive interviewing involves understanding how individuals interpret questions, retrieve relevant information, evaluate the information retrieved, and formulate a response to the question in order to provide a valid response[48]. This technique improves the question structure to resemble the way individuals structure information in their memories, thus improving questionnaire validity[48]. Revisions to the questions are made based on the findings from the cognitive interviews[48]. Field testing of new and revised questions is conducted after the cognitive interviewing pretest[48]. This provides an opportunity to ensure that the revisions made are appropriate and that the questionnaire flows smoothly[48].

Second, PRAMS integrates data entry verification into its protocol. Data entry verification is required for a minimum of 10% of mail surveys[30]. However, most states perform a greater percentage of mail survey verification to ensure high data quality[30]. PIDS allows for automatic range checks for erroneous data, as well as double-entry checks to identify keying errors[49]. Additionally, supervisors are required to monitor 10% of all telephone calls to make sure the survey is properly administered, and responses are properly recorded[30]. Telephone interviewer monitoring is critical because telephone interview data are vulnerable to bias from variability between interviewers and variability between interviews conducted by a single interviewer[48]. Having these monitoring procedures in place ensures consistency and quality of PRAMS questionnaire data[48].

Third, periodic evaluations of PRAMS data and operations are necessary to ensure data quality[48]. CDC and the states have roles in conducting these evaluations[54]. CDC conducts sampling

procedure evaluations annually and works closely with states to correct problems that are identified[54]. CDC evaluates sampling frame bias, selection bias, sampling fraction, and multiple birth selection[54]. The state evaluates PRAMS operational procedures on a consistent basis. This involves observing and reviewing the operational and data collection activities carried out by PRAMS staff, identifying deviations from protocol, identifying areas that may benefit from modification, and working with PRAMS staff to correct problem areas and put suggested modifications into practice[54].

PRAMS includes additional quality control measures, such as quality assurance of mailed surveys to make sure the right materials are in the right envelopes, data cleaning and editing to check for data entry errors and inconsistencies, and site visits to review results of operational evaluation analyses and observe PRAMS staff carry out daily operations[48 49 54]. PRAMS prohibits the data collection period to exceed 95 days to maintain data integrity[48]. Finally, CDC ensures consistency of content across all states and populations by being the single source of language translation for PRAMS questionnaire and accompanying materials[48].

(2) IRB Approval

Protection of human subjects is an essential component of PRAMS surveillance[53]. CDC obtains approval for the PRAMS project from the CDC Institutional Review Board (IRB)[30]. The CDC IRB reviews and approves the project's methodology and protocol on an annual basis. In addition, state PRAMS projects must undergo review by their local institutional review board for approval of their surveillance methodology[30 53]. All materials including the questionnaire, protocol, etc., must be presented to the local IRB[53]. Finally, any deviations from the PRAMS protocol must be approved by both the local and CDC institutional review boards before implementation[30]. Having a federal and state statutory assurance of the protection of human subjects is a factor that influences data quality and acceptability of the PRAMS surveillance system.

(3) Data Source

PRAMS data is derived from three sources: birth certificate data, operational data, and questionnaire data[48]. All three data sources are combined to create a final, weighted PRAMS analysis data set[48]. The birth certificate data contain information on selected maternal characteristics (i.e. race, ethnicity, age) and pregnancy outcomes (i.e. birth weight, gestational age)[9]. Women eligible to participate in PRAMS are selected from the state's birth certificate file[17]. Using states' birth certificates as its population-based sampling frame, PRAMS identifies a stratified sample of women several months postpartum that represents the population eligible for inclusion in the sample[47]. Inclusion criteria include being a resident in and delivering a live-born infant in a given state during the surveillance period[47]. By using the birth certificate file as the sampling frame, PRAMS implicitly excluded stillbirths, fetal deaths, and induced abortions[47]. Birth records not yet processed are not available for inclusion in the frame[47]. The sampling frame

is routinely checked for duplicated records to eliminate the possibility of an infant being included twice[47].

PRAMS operational data are generated by the customized tracking software, PIDS, to facilitate daily operations, operational evaluations, and analyses of survey methods[9 48]. Operational data includes mail activity, call attempts, scheduling, participation, and data consistency[54]. Operational data are used to calculate response rates, monitor quality of operations, and analyze PRAMS' survey methodology[48]. This data provides a good indication of how well PRAMS operational procedures are being carried out and whether the procedures are producing the desired results.

The PRAMS questionnaire serves as the primary source of maternal behavior information for the time before, during, and after a mother's most recent pregnancy[48]. Since the questionnaire data are self-reported two to eight months after delivery, responses might be subject to recall bias and nondisclosure of sensitive information[39]. For the subset of women who experienced pregnancy complications or whose infant experienced health problems, recall might differ from women who did not experience these health events[39]. Moreover, recall bias occurs particularly for behaviors and experiences that occurred early in the pregnancy[39]. Nondisclosure of sensitive information or behaviors perceived as socially undesirable (i.e. smoking and alcohol use) might result in underestimates of certain indicators[39].

(4) Data Completeness

By collecting data about the preconception and postpartum periods, in addition to the time during pregnancy, PRAMS has information on a wide range of risk factors that influence maternal and infant health[30]. Selected mothers may choose not to participate in the survey or not to answer a particular question, or multiple questions[23]. Consequently, PRAMS questionnaires may be returned incomplete. Questionnaires that are returned less than 75% complete must be followed up by telephone[48]. States may choose whether to follow up on incomplete questionnaires that are greater than or equal to 75%. They can mark the questionnaire as complete to end data collection or move it to the telephone queue for follow up[48]. For PRAMS, the item nonresponse rates remain very low (1-2%), meaning that the surveillance system can record data that is close to 100% completion[30].

(5) Response Rates Threshold & Sample Sizes

Response rates are crucial to the quality of the PRAMS surveillance system and its the ability to produce valid scientific analyses[48]. To ensure high quality data and motivate states to adhere to data collection protocol, CDC implemented a minimum overall response rate threshold for the release of data[30]. The threshold was set at 70% for years 2006 and earlier; subsequent levels were 65% (2007 to 2011), 60% (2012 to 2014), and 55% (2015 to present)[8]. The lowering of the response rate threshold corresponds accordingly to the decline in response rates for most federal health surveys[30]. These declines are consistent with findings suggesting that the public is becoming increasingly resistant to unsolicited surveys[30]. For any given year, the majority, but not all PRAMS

states meet the response rate threshold[30]. States that do not meet the threshold still receive their weighted data for internal use (i.e. program development, evaluation, and collaboration), but the information is not included in data released by CDC nor can it be presented outside the health departments in reports, publications and data made available to the public[30 49]. Consequently, the number of states with data available may vary from year to year. Compared to other mail surveys, PRAMS elicits high response rates because of its mixed methodology[47]. Based on the experiences of states conducting PRAMS, the expected response rates average between 60-70% for high-risk strata and between 65%-80% for low-risk strata[47].

Required sample sizes for PRAMS are determined in relation to the given population that is being estimated, at a given level of precision, and with a given level of statistical confidence[47]. On average, a sample size of about n=400 is necessary in each stratum for estimation with reasonable precision and 95% confidence[47]. A 95% confidence interval is critical to demonstrate the precision of estimates and provides the range of values that have a 95% probability for containing the true population percentage that is being estimated[27]. Mothers in some strata may be more difficult to contact than mothers in another strata[47]. As a result, actual sample sizes must be larger than theoretically needed to achieve a given level of statistical power[47]. Based on the estimates stratum-specific response rates, the stratum-specific sizes will be inflated to ensure an adequate number of responses for analysis[47]. Overall, each participating state samples between 1,300 and 3,400 women per year[3].

Appendix 26: Acceptability Key Themes, Detailed

(1) Respondent Participation

PRAMS is able to maintain high participation among mothers due its personalized mailing package, use of incentives and rewards, and repeated but varied contact attempts[31]. The latter two techniques have been proven to enhance response in controlled experimental settings[31]. Specifically, the use of response incentives and telephone follow-up have been shown to incrementally increase response rates by 8% to 19%[31]. Furthermore, the PRAMS questionnaire has government sponsorship, covers topics of high importance to new mothers, and acknowledges participant's contribution in playing an active role in improving the health and well-being of mothers and infants[31]. All of these factors have been shown to be positively associated with response and contribute to the high participation rate and low refusal rate achieved by PRAMS when compared to other health surveys using similar modes of administration[31].

PRAMS' contact rate ranges from 58% to 93% and its participation rates ranges from 86% to 97%, suggesting that once a sampled mother was contacted, she was usually willing to complete the survey[31]. In general, PRAMS participation rates are higher than its contact rates[31]. Participation rates are higher for white women than for black women, for married women than for unmarried women, for first-time mothers than for multiparous women, and for women who initiated prenatal care in the first trimester than for women with late or no prenatal care[31]. For most states, maternal

education is the most consistent predictor of participation, while birthweight and maternal age are poor predictors[31].

Participation burden should be considered when discussing respondent participation and is directly linked to the willingness of mothers to participate in the survey. To reduce the burden on participants, the mail questionnaire takes approximately 20 minutes to complete and the telephone interview requires approximately 25 to 30 minutes[30]. Additionally, the mail questionnaire is limited to 14 pages, double-sided as to not jeopardize the perceived size of the questionnaire[48]. There are no physical risks associated with participating in PRAMS[53]. However, the PRAMS questionnaire will obtain sensitive and individually identifiable data on mothers, which may affect willingness to participate and completion of the questionnaire due to confidentially[53].

(2) Site Participation

PRAMS is conducted through cooperative agreements between the CDC and participating state, territorial, tribal, or local health departments[17]. From its inception in 1987, the number of states participating in PRAMS has grown dramatically. PRAMS started with six participating sites: District of Columbia, Indiana, Maine, Michigan, Oklahoma, and West Virginia[44]. As of July 2020, PRAMS is active in 47 states, New York City, Puerto Rico, and the District of Columbia, representing approximately 83% of all U.S. live births[2]. Two other states (California and Ohio) previously participated, but then replaced PRAMS with their own pregnancy assessment surveys[10]. PRAMS participation in the majority of states is evidence of the acceptability and willingness to operate the surveillance system.

It is reported that PRAMS staff have high confidence in the effectiveness of the surveillance system. These individuals are responsible for PRAMS' operations and are committed to following proper protocols to guarantee success of the program. PRAMS staff have a genuine interest is how PRAMS data can contribute to maternal child health in their participating state. This interest is evident by the long PRAMS tenures and low staff turnovers.

(3) Privacy & Confidentiality

All survey responses are kept strictly confidential and private like all personal health information[23]. In all PRAMS communications, mothers are informed that their participation is voluntary and that their data will remain confidential and anonymous[29]. An informed consent document is included with each mailed survey packet explaining the participant's rights and privacy protection[30]. Consent is implied if a mother returns a completed questionnaire, requiring no written consent[30] [53]. Similarly, the informed consent is read verbally during phone interviews, and the participant must verbally agree to proceed with the survey[30].

Confidentiality begins with PRAMS staff training. All state staff and contractors involved in PRAMS are trained concerning procedures and practices to ensure privacy of data and must sign

a confidentiality pledge[53]. Staff must complete the CDC PRAMS Human Subjects Training to ensure the protection of human subjects, adherence to the PRAMS protocol, and understanding of the implications of breaches in protocol[53]. Refresher trainings are conducted at least once per year, and all modules are repeated in the case of a breach in protocol[53]. In addition, telephone interviewers are trained to maintain confidentiality and protect the mother's privacy since the interviewers will have contact with a mother's family or friends when calling a household[48]. In particular, the words "Pregnancy Risk Assessment Monitoring System" cannot be printed on any envelopes that are mailed to mothers or mentioned on the phone as this violates a woman's confidentiality, as the work "pregnancy" may be of concern. Instead, the acronym "PRAMS" is used[48].

Confidentiality continues to be maintained during data collection and storage. All information collected by PRAMS is held in confidence to the extent allowed by the law[22 25 53]. For electronic information, the PIDS system employs extensive security measures to protect personally identified information[48]. In addition, all software applications require a screen saver login, documentation of user login activity, and storage on a network accessible only by PRAMS staff[49]. Data is entered and stored in the PIDS system without any identifiers (i.e. birth certificate numbers, social security numbers)[49]. PIDS assigns a unique identifier called MomID for each record as a means of de-identification[49]. Identifying information (i.e. names and addresses) is used only for PRAMS operations, such as mailing and telephone interviews[20]. For paper documents containing personally identified information, states implement physical security measures to protect these files and documents, including storing completed questionnaires in locked cabinets, limiting access to authorized personnel, and destroying documents when no longer needed[49].

In PRAMS analytic data files and reports, responses are aggregated or grouped together to ensure that responses are not traced back to the mothers participating in the survey[30]. For example, no geographic indicators smaller than the state level are included in the analytic data files, maternal age is aggregated into 5-year groupings and only months and years are provided for date of birth[30]. Individually identifiable information is excluded from reports arising from analysis of data collection[22 25]. These measures are implemented to protect the confidentiality of all PRAMS participants.

(4) Public Health Importance

PRAMS public health importance and how its data is used are factors that influence the acceptability of the surveillance system. One of PRAMS' greatest strength is its ability to provide a conduit for community "voice" and to elevate the "need" in a geographic region[40]. PRAMS inquiries about women's attitudes, opinions and assessments, as well as behavioral and programmatic participation information[40]. This information embodies women's perceptions of their pregnancy-related experiences[40].

PRAMS data provides the ability to examine associations between risk factors and reproductive outcomes, explore disparities by subpopulations, and track key health indicators over time[30]. Participating states use PRAMS data to gain invaluable information to develop, implement, and evaluate new maternal and child health programs and to modify existing programs[20 23 30]. Furthermore, PRAMS data can be used to monitor participation of those programs and assess their impact[40]. States use information from PRAMS data to inform and influence public health policy relevant to reproductive health[18]. Research and public health professionals use PRAMS data to investigate emerging issues in the field of maternal and child health and incorporate the latest evidence-based findings into standards of practice[2 20]. Communities are also made aware of the prevalence of regional prenatal behaviors and experiences, increasing the public's awareness of important reproductive health issues[19 23 41].

PRAMS has the ability to identify groups of women at high-risk for adverse reproductive outcomes and infant health problems[44]. From a public health perspective, this information is critical for understanding how best to improve health care delivery, and the allocation and utilization of health resources in high-risk populations[2]. In addition, PRAMS provides ongoing monitoring of maternal behaviors. This allows states to examine trends and monitor changes of key health indicators over time (i.e. unintended pregnancy, prenatal care, breastfeeding, smoking, drinking, and infant health) [26 38]. Specifically, it allows states to monitor targets in Healthy People 2020, Title V National Performance Measures, preconception health and health care indicators, and selected performance measure for various public health initiatives[30]. The dissemination of PRAMS data to key stakeholders is critical in translating findings from the PRAMS surveillance system into public health action[12].

Appendix 27: Sensitivity Key Themes, Detailed

(1) Willingness to Report Status

All stakeholders agreed that participants are very willing to report their behaviors and experiences on the PRAMS survey. Participates have shown interest in the program, as well as the topics included in the questionnaire. They voluntarily share stories other mothers can relate to and information that will benefit the MCH community. Additionally, participants feel confident that the survey is anonymous and that their responses will remain confidential.

Some stakeholders referred to their high response rates as evidence of participates' willingness to engage with PRAMS and report their status. Others observed higher prevalence of sensitive issues on PRAMS than compared to birth certificates (i.e. smoking during pregnancy, breastfeeding, and use of drugs during pregnancy). A few stakeholders noted that willingness to accurately report status varied by subgroup and mode, especially for sensitive issues or behaviors that are viewed as socially unacceptable. For example, participants are more willing to answer questions truthfully on a self-administered, paper survey than other the phone with an interviewer administrating the survey.

(2) Ability to Understand Questions & Correctly Identify Status

All stakeholders reported that the majority of participants are able to understand the PRAMS questions and correctly identify their health condition and status. Participating sites had confidence in the surveillance system and the efforts applied to ensure that participants can easily understand the questions, apply them to their own experiences, and respond to the questions in the ways that were intended for data collection. A few of these efforts included the field testing of questions, the use of a lower reading level, and the availability of questionnaire guides.

Participating sites did not receive much feedback from respondents saying they did not understand the questions. If respondents did have questions, they would call their local PRAMS office, write comments on the survey or ask the interviewer for follow-up explanation during phone interviews. The comment data consists of mother's comments to the questions or their comments about answering questions related to their pregnancy[9]. In most cases, clarifying questions resulted from words in the survey that individuals did not fully understand or recognize (i.e. medical terminology). To alleviate misunderstanding, PRAMS provided simple definitions to help with explaining or clarifying questions if the respondent did not understand.

A few stakeholders mentioned having to clarify the timeframe in question on the survey. Some questions on the survey are very similar but use different timeframes (i.e. before, during or after pregnancy). To distinguish the separate timeframes, PRAMS designed its survey so that before pregnancy questions are at the beginning of the survey, during pregnancy questions are in the middle, and postpartum questions are at the end. Furthermore, language was identified as a barrier for some participating sites with growing diverse communities that might not have English or Spanish as their primary language. One stakeholder mentioned that there is still room for improvement, especially with individuals from disparate groups or that speak other languages.

(3) Validation of Data Collected

CDC holds the responsibility of cleaning and analyzing the data collected by the surveillance system to determine usability[50]. At the CDC-level, some data validation occurs when preparing the weighed data set for each participating site. At the state-level, most participating sites reported that there is no established, systematic way of validating data collected through the surveillance system. Sites have created their own validation process by comparing PRAMS data with data usually external to the system, such as birth certificate data, WIC data, discharge data, demographic registry, BRFSS, etc. Birth certificate data was frequently mentioned as a common source of data validation. The PRAMS data was compared with birth certificates as the standard because the comparison of data might provide insight about improving the accuracy and quality of PRAMS data[4]. The objective was to compare selected PRAMS indicators with other analogous data sets around the same population and related to pregnancy. It was not possible to validate all indicators reported on the PRAMS questionnaire because for some indicators, there were no comparable data sources. Some sites compared PRAMS data with data from previous years to

check for consistencies and unusual patterns in the data. Others perform descriptive frequencies to check some of the demographic indicators and selected health indicators. One stakeholder reported doing cross checks of frequencies and responses from PRAMS with information from other sources and that the variables were consistent between the sources.

All participating sites follow protocol to validate that PRAMS surveys are completed by the intended participant. For mail surveys, there was a general assumption that the surveys were going to the individuals they were addressed to. Sites must rely on having the correct mailing address to reach participants. Upon receiving the mailed survey, each participant was asked to verify information to confirm that they are the intended recipient of the survey. This information included date of birth of the mother and date of birth of the infant. PRAMS staff then use this information to match the survey number and dates of births with what is on record. Similarly to the mailed survey, phone interviewers were required to follow the protocol to make sure they are speaking with the right person, such as confirming the participant's name, date of birth, and address. Some stakeholders mentioned that it is easier to validate the participant during the phone interviews than via mail. A few sites mentioned discrepancies with the date of birth checks. When discrepancies occur, PRAMS staff reviewed the data on a case-by-case bases to identify the source of error and determine how to handle the survey. A few sites mentioned that they do not accept surveys if they cannot without reasonable certainty verify the respondent. One site mentioned they are confident in data validation via phone interviews, but not confident in data validation via mail survey.

Appendix 28: Positive Predictive Value Key Themes, Detailed

(1) Confirmation of Cases

All stakeholders reported that the PRAMS protocol does not require investigations of cases reported through the surveillance system. As a result, most participating sites developed their own investigations to confirm health-related behaviors and experiences reported through PRAMS. The process of confirming cases varied across all participating sites. Most sites used other data sources at their disposal to confirm selected PRAMS indicators. The most common data sources recognized as gold standards were medical records and birth certificates. Other data sources included WIC data, Medicaid data, and other survey data. A consideration for some stakeholders was that these data sources collect information from the entire population, while PRAMS is focused on a specific population of women who just gave birth. Many stakeholders acknowledged the limitations of these data sources, indicating that no one data source is perfect and that all are subjected to biases and human errors. Some participating sites noted that these case investigations were not routine.

A few stakeholders expressed concerns with the difficulty of confirming cases. Since responses to the PRASM survey are not collected in-person, it was challenging to confirm individual data through tests. Instead, participating sites relied on aggregated estimates to confirm patterns. Many share data with their local communities and practitioners to observe if what local end users are

seeing in practice is comparable to what is reported through PRAMS. Stakeholders reported feeling more confident in PRAMS data when it matched other data sets and what others are seeing in the community. Additionally, participating sites have engaged in specific investigations around a topic of interest and developed focus groups to explore topics in greater detail. One stakeholder suggested that interviews could be used to confirm cases and described the additional resources case investigations would require (i.e. funding).

(2) Prevalence of Health-Related Events

Several stakeholders acknowledged that PRAMS does a satisfactory job at reflecting the prevalence of some health indicators and not do so well for other indicators. This aligns with research findings in the literature. One study found PRAMS data to provide reasonable prevalence estimates for selected indicators, such as pre-pregnancy BMI and gestational weight gain[36]. Other studies found that PRAMS underestimated the true prevalence of indicators, such as unintended pregnancies and physical abuse[39]. For other selected indicators, it was impractical to compare PRAMS' prevalence estimates to another source because PRAMS was the only or one of the few data sources for such indicators (i.e. barriers to prenatal care and postpartum care)[30].

Appendix 29: Representativeness Key Themes, Detailed

(1) Generalizability

PRAMS is designed to provide statewide estimates[50]. Since random samples are chosen from all women who had a live birth recently, the sample population is diverse, and findings can be applied to the state's entire population of women who have recently delivered a live-born infant[13]. States use weighted estimates to ensure that results are representative of women who are residents of the state and gave birth during the surveillance period[27 29 37].

It is important to understand the effects of sampling frame exclusions on potential generalizability of the results to the total birth population. Since PRAMS provides population-based data for each participating state, results cannot be generalized to other states or to the United States as a whole[39]. Moreover, it may not be suitable for analyses of very small geographic regions, such as counties[50]. PRAMS findings are not generalizable to women whose pregnancies did not result in a live birth (i.e. abortion, stillbirths, and fetal deaths)[39]. Thus, the prevalence of some risk behaviors among all pregnant women might be higher or lower than reported by PRAMS[39].

(2) Population of Interest

The population of interest for each PRAMS state is resident women who recently gave birth within the state to a live-born infant during the surveillance year[47]. These inclusion criteria are critical for identifying PRAMS' sampling frame. Using the aforementioned criteria, a stratified, randomized sample of mothers is identified each month to complete the survey[35]. These women are a diverse

group, representing mothers across age ranges, races and ethnicities, education and socioeconomic status.

For PRAMS surveillance, there is often particular interest in certain subgroups form a public health perspective[47]. Participating sites stratify their sample according to their own priorities[47]. Stratification variables include characteristics of public health interest, such as maternal age, race/ethnicity, geographic area of residence, maternal education, Medicaid status, and infant birth weight[47]. Some subgroups may not represent a large portion of a state's overall population, and therefore are sampled at a higher rate so that inferences can be made[47]. Stratified sampling permits separate estimates of subgroups of interest and comparisons across these subgroups by ensuring that that subgroups are adequately represented in the sample for analysis[47].

Exclusions are made to identify population characteristics not included in PRAMS. Since PRAMS only surveys women who delivered live births, PRAMS data do not represent women who had miscarriages or stillbirths[38]. Out of state births are restricted from PRAMS because there are often substantial delays in obtain birth certificate information from other states[47]. In most cases, records are obtained too late to be sampled and followed up within the two to six month timeframe prescribed in the data collection protocol[47]. In-state births of nonresidents are excluded because the state's target population for public health action is its residents and does not extend beyond state boarders[47]. Information on state residents is more relevant for serving the needs of the state[47].

Additional exclusions include adopted infants, surrogate births, infants of multiple gestations, and delayed processing of birth certificates[47]. As the majority of the survey questions involve the time period prior to and during pregnancy, adoptive mothers do not qualify to respond to the survey[47]. A similar logic applies to surrogate births. In most cases, the intended mother (the women who will raise the child) is named on the birth certificate and does not qualify to participate in PRAMS[47]. Infants of a multiple gestation have the same intrauterine environment and are not independent of one another[47]. PRAMS established measures to ensure that only one infant of a multiple gestation is included in the sampling frame[47]. Birth certificates that are processed too late after the birth occurred (more than six months) are excluded from the sample frame as the use of these records raise concerns about recall bias, ability to locate the mother, and comparability with other respondents[47].

(3) Errors & Biases

PRAMS questionnaire data are self-reported and may be subject to inaccurate reporting and biases[50]. These inaccuracies may occur for a variety of reasons and have effects on the findings. For starters, the interpretation of PRAMS question is left up to the respondents. The questionnaire does not instruct women in the meaning of questions. If women interpret the question differently than expected, or some subgroups interpret the question differently than others, inaccurate information may result.

Recall bias occurs when respondents asked about events in the past do not remember them accurately[50]. Reporting bias occurs when respondents are unwilling to report some behaviors or events (i.e. smoking), or they may over report socially desirable behaviors (i.e. car seat use)[50]. Mode bias occurs if a respondent who completes the telephone interview answers differently than they would have if they had completed the self-administered questionnaire[50]. Noncoverage bias occurs when certain groups are underrepresented in the study sample and could arise if birth certificate records from one area of the state are systematically excluded from the sample because of a delay in submitting records to the state health department[50].

Nonresponse bias occurs when some subgroups of the sample do not respond to the PRAMS survey or are less likely to respond than other groups[50]. Often, the characteristics of women who are hardest to reach are also the characteristics associated with higher risk of poor birth outcomes[31]. PRAMS addresses nonresponse bias by using weights to adjust for identified differences in responses[50]. These weights assume that the women in a particular subgroup who responded have the same responses as those who did not respond[50]. Additionally, PRAMS identifies high-risk groups that may be poorly represented and focus efforts on improving responses among those groups[31].

Appendix 30: Timeliness Key Themes, Detailed

(1) Surveillance System Time Intervals

There are several time intervals that were examined when considering timeliness of the PRAMS surveillance system. The time interval considered first is the amount of time between the health-related event (a live birth) and the administration of the PRAMS survey. The series of mailings typically commences mailed two to four months after delivery of a live-born infant[47]. To collect information about factors that occur in early infancy, mothers are contacted no earlier than two months after delivery to ensure all mothers are able to respond for this period[47]. This time interval is satisfactory because it allows for the collection of information about postpartum maternal and infant experiences[3 38 39].

The second time interval to consider is the data collection cycle. The cycle from the mailing of the pre-letter to the close of telephone follow-up lasts approximately 60-95 days and is repeated each month during the surveillance year[3]. A data collection period of 95 days means that the infants are up to six months old when data collection ceases. To reduce concerns of recall bias, CDC recommends that questionnaires be completed six months after delivery[48]. Questionnaires completed after nine months of delivery will not be accepted[48]. With timely sampling procedures and implementation of data collection procedures, very few, if any, questionnaires are completed six months beyond delivery[48]. For a given surveillance year, the data collection is completed by July of the following year to allow time to gather postpartum information[30].

The third time interval to consider is the timeframe for making PRAMS data available to states. Under the current protocol, weighted PRAMS data is available to all states approximately 6-12

months after the completion of data collection in a given year[30]. For example, data collection for 2018 births was completed in July 2019 and the data set was released in 2020. This time interval is prolonged because it is dependent upon closeout activities, such as the receipt of cleaned, edited data files and the final-year birth files from participating sites[49].

(2) Identification of Trends and Intervention Effectiveness

Another aspect of timeliness is the time required for the identification of trends and the effect of control and prevention measures. PRAMS collects a year-worth of data before data is weighted and disseminated. As previously mentioned, this process is prolonged and the weighted data is generally available two years after the end of each birth year. This protracted timeline may be suitable for identifying trends in chronic diseases that are consistent over time (i.e. obesity, diabetes and hypertension). The extended timeline becomes a concern for emerging issues such as opioid epidemic, coronavirus pandemic and outbreaks. For emerging issues, timely data is critical for understanding how these issues are impacting the maternal and child health population. The delayed data provided by PRAMS may not be suitable for urgent issues as the way we talk about these issues may change quickly over time. Additionally, it creates challenges for states that need to use PRAMS data for timely decision-making in response to current and emergent public health threats[32]. Responses may include immediate control efforts, prevention of continued exposure, program planning and policies.

Availability of timely information is also critical in the evaluation of control and prevention measures. PRAMS is often used to assess the effectiveness of intervention measures on the maternal and child health population. Trends in PRAMS data can provide baselines for comparison and provide insight into the health indicator of interest prior to the intervention[38]. After implementation of the intervention, PRAMS data can then provide insight on the impact of the intervention[40]. The level of timeliness for the evaluation of control and prevention efforts is dependent on the type of intervention and how long it takes for the intervention to have impact on the population. It is likely that several years of PRAMS data is needed to validate the effectiveness of an MCH intervention.

(3) Start-Up and Revision Timelines

PRAMS start up activities is an extensive process and takes approximately 10-14 months from initial CDC funding to commencing data collection[52]. During this start-up period, the states are completing major tasks, such as hiring and training staff, developing state protocol, organizing and convening a steering committee, undergoing IRB review, and selecting state-specific questions[52]. These activities need to begin immediately after funding is received to ensure successful and timely implementation of the PRAMS program[52].

Once the surveillance system is fully operational, it undergoes periodic revisions every three to five years[30]. The PRAMS questionnaire revision process typically begins two years in advance[30]. During this review process, CDC evaluates current questions, solicits requests for new topics or

enhanced questions on existing topics, and complete cognitive and field testing[30]. About a year prior to going live with a new survey, CDC begins preparing the individual surveys for each participating site[30]. For example, mail and phone versions of each site's survey in English and Spanish (if applicable) are created by the CDC[30]. The PIDS software system is also programmed during this time to allow for data entry of mail surveys and administration of telephone surveys[30].

Appendix 31: Stability Key Themes, Detailed

(1) System Longevity

PRAMS was initiated in 1987 and continues to be an ongoing project of the Centers for Disease Control and Prevention (CDC) with state health departments[38]. PRAMS, which recently completed its 33rd consecutive year of surveillance, continues to be a comprehensive source of perinatal data and has proven to be an effective system for addressing emerging issues affecting the health of mothers and babies. PRAMS has grown dramatically in recent years, expanding from 6 participating sites to 50 participating sites across the United States.

When asked about utilization of the system and operations, stakeholders agreed that PRAMS is readily available and is functional when needed. The consensus was that PRAMS is fully operational 90% of the time or greater. The system functions appropriately and fulfills the purpose of its design. It allows participating sites to collect data on maternal and child health and use the data to make informed decisions for their geographic location.

(2) Data Release & Availability

For PRAMS data to be effective, it must be provided to end users in a form that can be easily accessible and utilized[50]. During the early development of PRAMS, states were encouraged to identify individuals and groups who should receive PRAMS data, the topics of interest to those groups, and the most effective media types and formats for reaching those groups[50]. These identified stakeholders included data users, program planners, policy developers, health care providers, researchers, state provider associations, the PRAMS Steering Committee, and other interested parties[50]. Common media formats include press releases, state reports, graphs, presentations, posters, articles, manuscripts, fact sheets and brochures[50]. These formats vary depending on the target audience (i.e. general public, legislature, public health and health care professionals)[50]. Most states publish annually PRAMS reports and focus briefs that are easily accessible online via state health department websites[17 26 28].

Participating sites that meet the established response rate threshold are included in multistate analytic data sets provided by CDC[30]. Public use of the multistate analytic data set is available upon request from CDC through a proposal submission process[30]. Each proposal must include an application form, abstract, and signed data sharing agreement[9]. Proposals are reviewed by a member of the CDC PRAMS team regarding the suitability of PRAMS data for the proposed analysis and the appropriateness of the analysis plan considering the PRAMS survey design[9]. Once

approved by CDC, the proposal is distributed to sites for review, and the analysis data set is sent to the requester[9]. Individuals can also directly contact participating sites to request access to local data or data not included in the master analytic data set[30]. Furthermore, selected PRAMS variables are available online for public use[30].

(3) Dedicated Resources

PRAMS requires dedicated resources to ensure the success of the surveillance system program. The critical resources cited by stakeholders were funding and staffing. There was consensus that funding provided by CDC was not enough to support a full PRAMS program. The expectation was that states will invest in their surveillance systems and request additional funding from programs that rely on PRAMS data (i.e. Title V Maternal and Child Health Block Grant). Participating sites varied in their views of resource allocation. Some reported having appropriate resources at the state-level, as well as at the CDC-level. These sites felt the PRAMS program was fully supported and had enough resources to effectively operate the program. Other sites described having public health infrastructures that were underfunded and did not have extra resources to allocate to PRAMS data collection. These sites reported that they struggle to maintain the CDC recommendation for response rates with their existing resources. Efforts to increase response rates would require more staff time and additional funding to do things like sustain consistent incentives and rewards. All stakeholders agreed that more funding would be helpful so that participating sites can do more recruitment activities to broaden the sample size and increase participation.

Regarding staffing, the PRAMS protocol called for each participating site to have a minimum of two full-time staff members to carry out most aspects of PRAMS data collection: a project coordinator and a data manager[31]. The project coordinator spends 60-100% of their time on PRAMS and has primary responsibility for the day-to-day management of PRAMS, including training and supervising staff, acting as liaison between the state and the CDC in matters relating to PRAMS, overseeing the development of the state's PRAMS protocol, and managing contracts, if applicable[46]. The data manager spends 100% of their time on PRAMS and is responsible for the day-to-day PRAMS operational activities, including data collection and management[46]. Some states may require additional support staff beyond the project coordinator and data manager to support daily PRAMS operations, including telephone interviewers, data entry staff, temporary workers, and staff to assist with mailings[46].

Sites have the option of keeping their PRAMS operation in-house or outsourcing their operations to a contractor. Each option has its unique considerations. A consideration of in-house operations is that staff can quickly flex their responses to the program demands (i.e. creating mailers, conducting phone interviews, etc.). Some sites find outsourcing as the more favorable option to offset the numerous and simultaneous processes required by the PRAMS program. However, cost was noted as a barrier and a major consideration for contracting services. Both options, in-house or contracting, ensure continued operations and that dedicated staff was assigned to PRAMS surveillance.

(4) System Downtime

PRAMS has experienced very few interruptions to its data collection system and overall operations. Many stakeholders described scheduled and unscheduled downtimes to be limited in frequency and duration. Scheduled downtimes usually occur for routine maintenances, upgrades or to resolve technical issues within PIDS. During these situations, CDC sends clear notifications in advance to participating sites informing them of when the system will be down and when it has returned online. This allows sites to anticipate downtimes and plan accordingly. Participating sites are able to work around downtimes by switching to manual processes (i.e. hardcopies). Stakeholders have witnessed fewer scheduled downtime with PIDS in recent years. They cite the 2012 installation of PIDS as being the longest scheduled downtime of the PRAMS surveillance system.

Unscheduled downtimes are reported to occur periodically throughout the year and for various reasons. A few reasons include problems and delays with PIDS, connectivity issues, contract lapses, and staff retirement or resignation. Stakeholders cited the 2020 Coronavirus pandemic as an unscheduled downtime that caused some states to temporarily pause operations. Despite these unscheduled downtimes, all stakeholders agreed that these interruptions did not prevent the program from collecting data or cause delay in the overall PRAMS operations. Staff try their best to continue operations manually and have planned redundancies in their processes to account for downtimes.

Curriculum Vitae

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PROFESSIONAL SUMMARY

Public health professional with extensive experience in leading teams toward organizational goals and objectives. Trusted and driven manager and team-builder with a unique ability to connect colleagues at all levels.

- 10+ years of experience carrying out diverse healthcare and public health functions (i.e. population health management, hospital administration, quality and safety, performance improvement, strategy, business planning, program development, clinical and non-clinical operations, emergency preparedness and executive administration).
- 6 years of specialized experience in project management, leading high-profiled projects, ensuring integration with other organizational initiatives and meeting objectives.
- 5 years of advanced public health training and knowledge of best practices.
- Proficient in management skills and techniques, including budgeting, supervising, prioritizing, delegating responsibilities, multi-tasking and collaborating with diverse stakeholder groups.
- Demonstrates superb leadership attributes (i.e. effective communication and presentation skills, decision making, strategic planning, professionalism, ability to drive business change, and continuous improvement.)
- Exemplary problem-solving skills; able to identify problems and implement corrective actions.
- Excellent strategic and process thinking abilities with an emphasis on building partnerships and working collaboratively with stakeholders.
- Excellent interpersonal and communication skills with demonstrated credibility to motivate and influence at all levels, internal and external to an organization.

EDUCATION

Doctor of Public Health — April 2021 (Expected)
Johns Hopkins Bloomberg School of Public Health | Baltimore, MD
Department: Health Policy and Management
Concentration: Healthcare Management and Leadership

Master of Public Health — December 2014
University of Pittsburgh | Pittsburgh, PA
Department: Health Policy & Management

Bachelor of Arts — May 2012
University of Pennsylvania | Philadelphia, PA
Major: Psychology; Minor: Biology

PROFESSIONAL EXPERIENCE

Project Manager - Enterprise PMO October 2017 - Present
Children's National Hospital | Washington DC, DC

Collaborates with the hospital's executive leadership team to define and deliver strategic initiatives related to organizational goals.
Duties

- Serves as the lead on complex, end-to-end projects, developing planning and implementation strategies to ensure projects are on time, on budget and within scope.
- Accountable for all project activities and follow-up as appropriate to ensure that expectations and commitments are fulfilled, and deadlines are met.
- Identifies current and emerging concerns impacting the organization and develops strategies to mitigate critical issues, escalating issues and providing recommendations as appropriate.
- Responsible for all project work plan development activities including, but not limited to, schedules/timelines, budget preparation/execution, operational plans, communication plans, risk management plans, workflow process redesign, metric development and measurement, workforce management, and resource allocations.
- Consults on the direction of program operations and policies, providing management and operational leadership of services and activities.
- Establishes departmental strategic priorities and goals for new fiscal years.
- Provides consultation on the development, recommendation, implementation, and interpretation of policies and procedures.
- Continuously evaluates and monitors key performance indicators and outcomes of intervention strategies.
- Uses data and clinical effectiveness approaches to improve quality and safety, applying qualitative and quantitative methods when applicable.
- Assembles project teams and directs all project activities, providing management continuity throughout all project phases.
- Leads multidisciplinary teams and external vendors/contractors to facilitate organizational projects and complete deliverables.
- Assigns project tasks to designated team members and manages project staff as assigned.
- Serves as a liaison for the organization, the department and the project on information management coordination, as well as between executive leadership and front-line staff.
- Provides regular project status reports/presentations and develops briefings to communicate technical information to internal and external stakeholders, including executive sponsors and board members.
- Facilitates steering committees, task forces, and working groups on behalf of executive vice presidents and chiefs.

Key Accomplishments
COVID-19 Mitigation

- Partnered with the Vice President and Chief Strategy Officer to develop a population health program trailered to local schools, educators, parents and community providers as it related to returning to school amid COVID-19.
- Provided direct support to the Executive Vice President of Operations Integration in response to COVID-19.
- Organized the hospital's emergency response into 7 key focus areas: Clinical & Operations, Supplies & Equipment, Human Resources & Occupational Health, Emergency Preparedness, Communication & Education, International & Travel, Monitoring & Metrics.

- Led and facilitated three key focus areas: Communication & Education, International & Travel, and Supplies & Equipment, including facilitated team meetings, completing follow-up actions, and reporting group outcomes.
- Supported the hospital's Command Center/Situation Room by participating in daily briefings.
- Stood up the ED COVID Tent for patient screening and testing. Assisted with procurement of essential supplies, equipment and furniture for rapid deployment.
- Researched legislation and updated guidelines to determine operational impacts, as well as ensure consistent, up-to-date communication (i.e. N95 and face shield reuse).
- Developed, implemented and staffed new processes for visitor screening, including required COVID screening questions and temperature checks.
- Partnered with Construction and Facilities to install protective barriers at 65+ locations at the hospital and off-site campuses, saving the organization $155,000 in contractor services.
- Led ad hoc projects as assigned.

Business Continuity Planning (BCP)

- Serves as an organization's BCP leader from 2018 to present.
- Developed and implemented a coordinated strategy to ensure continuity of business operations and the recovery of the facility during a disruption to normal operations.
- Analyzed established BCP programs and recommended strategies which were approved and adopted by the organization.
- Developed a multiyear project plan that included the formation of an organizational BCP framework, a phased project strategy, and involvement from 40+ departments.
- Continuously monitors project metrics and progress toward annual project goals.
- Formed a BCP steering committee that meets quarterly. Schedules and leads steering committee meetings. Prepares meeting documents, including agendas and presentations. Facilities meetings and follow-up on all action items.
- Designed and planned a 4-hour tabletop exercise in October 2019 with 60 participants from 35 departments including the COO.
- Saved the organization the cost of Business Continuity consultation services.

Ambulatory Relocation

- Spearheaded a $10.7M project to relocate 5 outpatient services from the main hospital to a new ambulatory location located in Takoma Park, Washington DC.
- Served as the point person for all project activities including marketing, communication, workforce management, clinic operations, environmental services, nursing, security, supply chain, parking solutions, space planning, construction, IT, pharmacy and external vendors.
- Scheduled and facilitated bi-weekly meetings with key stakeholders to plan operational readiness, discussing all necessary considerations for opening a new ambulatory clinic.
- Identified project activities that may adversely impact the project and provided solutions to alleviate future concerns.
- Addressed unforeseen project and end user issues with urgency, while staying within budget, timeline and scope.
- Ensured a successful opening in June 2020 while implementing COVID precautions, such as social distancing, increasing frequency of cleaning, reducing patient wait times and implementing appropriate visitor screening practices.

MIBG Therapy

- Worked with a multidisciplinary team to develop a business proposal for establishing a new treatment for advance stage neuroblastoma at Children's National. The business proposal includes a SWOT analysis, market analysis, operational impacts, capital investments, financial analysis and ROI, floor plan designs and project timeline.

- Presented the business proposal to executive leadership. It was approved in February 2019.
- Scheduled regular design meetings and provided project status updates as appropriate.
- Worked directly with architects and vendors to identify risks/issues and finalize project phases and costs ($4.2M).

Inpatient Psychiatric Unit Renovation

- Led a $13M renovation project of the Inpatient Child & Adolescent Psychiatric Unit.
- Worked closely with senior leadership, unit staff, construction, architects, vendors, IT, environmental services, risk management, regulatory, facilities, security and PR & Marketing to ensure the project reached completion.
- Provided project updates to executive leadership upon request.
- Coordinated all move day activities as well as a grand opening celebration in February 2018

Project Manager - Nursing Administration May 2016 – September 2017
Cleveland Clinic | Cleveland, OH

Supported the Chief Nursing Officer in establishing the strategic vision of the department.
Duties

- Served as point of contact for multiple medium to large size multi-disciplinary projects.
- Created and maintained project plans from inception through completion.
- Set and continually managed project expectations with team members and key stakeholders.
- Achieved operational objectives by identifying strategies and implementing change.

Key Accomplishments
Enterprise Sterile Processing Standardization

- Facilitated the strategic planning for the centralization and standardization of existing SPD services.
- Redesigned the current model to enhance patient safety by eliminating risk, providing high reliability, and maintaining high standards for such services throughout the enterprise.
- Prepared a project plan which included new processes and construction, allowing the organization to pass Joint Commission inspections and avoid shutting down its ENT services.

Preference Card Program

- Created an enterprise strategy and process for the cleanup and usage of preference cards, with the goal of reducing medical supplies expenditure.
- Developed a sustainable preference card program that supports long-term governance, standardization, and maintenance.
- Established roles and responsibilities between key stakeholders (i.e. administrative team, OpTime team, super users).
- Developed and communicated project timelines to leadership, team members and super users.
- Lead a team of 7 stakeholders though an 8-week quality & continuous improvement course (Solve), with the goal of developing a maintenance strategy for preference cards. The team completed a current status and future state analysis, identified barriers in the current process and appropriate countermeasures, selected key performance indicators and developed an implementation timeline.
- Monitored project progress across main campus and off-site locations.
- Saw a 4% reduction in cost per case from starting baseline (annualized savings: $126K)

Administrative Fellow - Executive Administration June 2015 – May 2016
Cleveland Clinic | Cleveland, OH

Completed a post-graduate training program that offered outstanding opportunities in a variety of leading-edge areas in healthcare management.
Duties

- Provided project management and support at the institute- and enterprise-level.
- Worked closely with senior leadership and key stakeholders on initiatives and strategic advancements.
- Created business proposals, operating models, presentations, reports, and project management tools.
- Analyzed and interpreted multifaceted data and made recommendations to stakeholders.
- Participated in leadership development activities (i.e. rounding, coaching, and mentoring)
- Worked with multidisciplinary teams to address challenges and create progressive solutions.

Key Accomplishments
Integrated Wellness Strategy

- Redesigned the current & future state of Wellness for the Cleveland Clinic.
- Engaged with key stakeholders to develop an enterprise-wide integrated wellness strategy.
- Identified opportunities to infuse wellness into the care model.
- Created a market strategy, product inventory, and organizational model.

Enterprise Surgical Scheduling Improvement

- Assessed potential savings of coordinating surgical scheduling at an enterprise-level.
- Conducted and presented data analyses to define FTE productivity and developing recommendations for senior leadership.

Blood Bank Expansion

- Coordinated the development of a business plan to optimize and expand the blood bank at Main Campus and eight regional hospitals.
- Created a proposal to right-size the needs of the department with FTEs, equipment and technology.

Intermediate Admin Assistant September 2014 – April 2015
University of Pittsburgh Physicians at UPMC | Pittsburgh, PA

Collaborated with the Director of Operations to provide administrative support to the Women Care Associates Department.
Duties and Accomplishments

- Worked closely with the stakeholders to initiate and lead projects.
- Implemented and managed the AMiON On-Call Scheduler project.
- Collected, complied, and analyzed complex data sets involving patient experience, staff performance, and patient volume trends.

Administrative Intern June 2014 – August 2014
The University of Pittsburgh Medical Center | Pittsburgh, PA

Collaborated with the Executive Director of Women's Health to carry out departmental functions.
Duties and Accomplishments

- Participated in the development and implementation of a new outpatient program: The Pregnancy Recovery Center.
- Provided project management support to various departments, such as Quality & Patient Safety, Patient Care Services, and Operations.
- Created presentations for staff, executives, and guests.
- Initiated and designed marketing strategies.
- Contributed to meetings at the staff-, departmental-, and executive-level.

PROFESSIONAL ASSOCIATIONS

National Association of Health Services Executives Spring 2018 to Present
Delta Sigma Theta Sorority, Incorporated Spring 2011 to Present

SCHOLARSHIPS

Gates Millennium Scholar Fall 2008 to Present
A national academic scholarship presented annually to provide opportunities for outstanding minority students, promote academic excellence, and increase representation of target groups in public health and science.

CERTIFICATIONS

Certificate in Lean Healthcare March 2018
Healthcare Performance Partners

Certification in Public Health February 2015
The National Board of Public Health Examiners